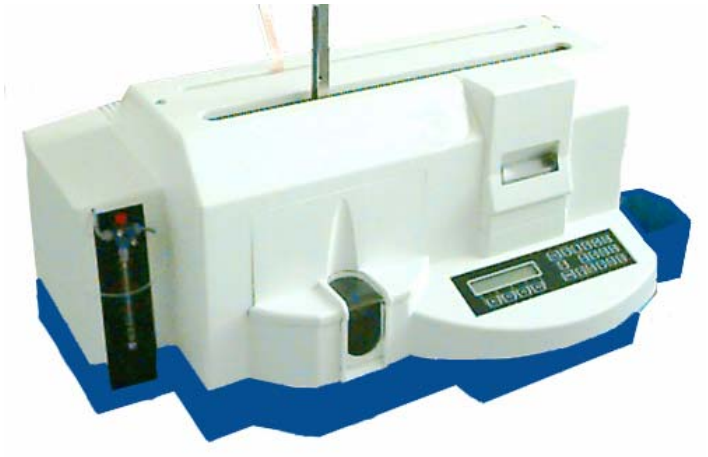
Operators Manual

CoaLAB 6000

For *in-vitro* diagnostic use only!



Order

Bedienungsanleitung CoaLAB 6000	Best. Nr.: 30.000.1615	German Version
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Revision History

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1.3	07/17/01	1.02d	Software update/corrections
1.4	05/07/02	1.03	Software update/corrections
1.5	08/12/02	1.03	Corrections
1.6	02/06/03	1.04	Software update/corrections
1.7	08/21/03	1.04	IVD update
1.8	11/26/04	1.04	Updates/Corrections

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Your Distributor:

(Please do not hesitate to contact your local distributor if you have any questions or problems.)

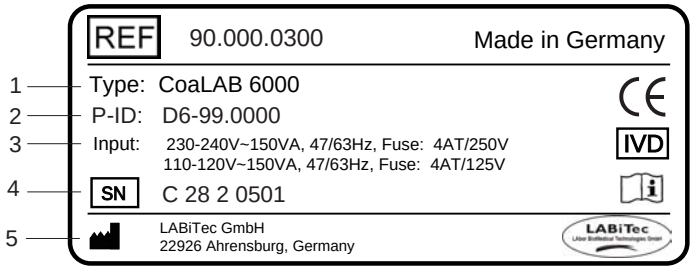
CoaLAB 6000

The name and serial number of your system can be found on the plate located on the back of the instrument.

Legend:

1 Type
2 Product Identification
3 Input
- Voltage (V)
- Power consumption (VA)
- Frequency (Hz)
- Fuses

4 Serial Number coded*
5 IVD Manufacturer



***** Serial number code:
e.g. C 28 2 0501

C Productions month
28 Production date
2 Production year
0501 consecutive instrument number

Please enter the following information:

Serial number: _____

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1 Introduction

The instrument type CoaLAB 6000 (in the following titled as analyzer/system) is a compact and automatic blood coagulation analyzer for routine and STAT samples in the clinical laboratory.

For *in-vitro* diagnostic use only!

The system can perform 3 clotting tests such as PT / aPTT and Fibrinogen simultaneously. It can perform additional tests such as Thrombin Time, when the ChipCARD is used to replace any of the 3 standard tests. The system can work in batch mode (individual test handling) or in random-access mode simultaneous test handling). In both cases the analyzer will manage the results automatically.

The analyzer has 6 digital measuring channels based on the turbodensitometric **FIBRINTIMER**™ measuring principle.

To avoid sedimentation a Teflon stirrer (2 stirrers are included) can be added to the reagent. The reagent positions are always at room temperature.

Purpose of this instruction manual

The instruction manual describes the system and is directed to all users of the system.

This instruction manual gives all information necessary for the installation, operation, maintenance, storing, packing, and transport of the system. Service information is handled separately.

Careful observation of all information, especially of hazards and precautions will ensure the correct and safe operation of the analyzer.

Therefore it is absolutely necessary to read the instruction manual completely.

This instruction manual was prepared with greatest care. Should you have any questions please refer to your distributor or to the manufacturer.

Validity of this instruction manual

All information in this instruction manual refers to this system:
For all requests please indicate type and serial number of your system which can be found on the type plate on the back of the instrument or under ‘identification’ of this manual.

1.1 Definitions

In this manual the following terms are used:

Analyzer/System/ Instrument

This is the CoaLAB 6000.

Manufacturer

The manufacturer according to IVD directive 98/79/EC is the company/dealer who distributes the system within the respective country.

User

User is the current operator of the instrument.

Personnel

Personnel are all people authorised to work with the system and meeting the specifications required by the manufacturer for the operation of the system.

Skilled personnel

All people who are especially qualified and authorised to handle specific matters in connection with the instrument.

Life phases

All phases of the system from end of manufacture to disposal of the instrument.

In this instruction manual all phases of the system will be mentioned.

QUALIFICATION OF PERSONNEL

The different life phases of the system require different qualifications of the personnel. The minimum requirements for qualification are described at the beginning of each chapter or at the proper place in this manual.

1.2 Description of the system

The System

No additional equipment is necessary to operate the instrument. The integrated module and system software controls the system and manages all data. The system can be connected to a host computer for the management of results. All measured results, reagent and test-specific data can be printed on the internal thermal printer.

The system will be loaded with samples, reagents, and cuvette bars. The samples in primary tubes (Becton Dickinson Vacutainer, Sarstedt Monovette or specially designed sample cups) are loaded into the sample rotor. At any time STAT samples can be loaded for priority handling. The system can either work sample-orientated or test-selective.

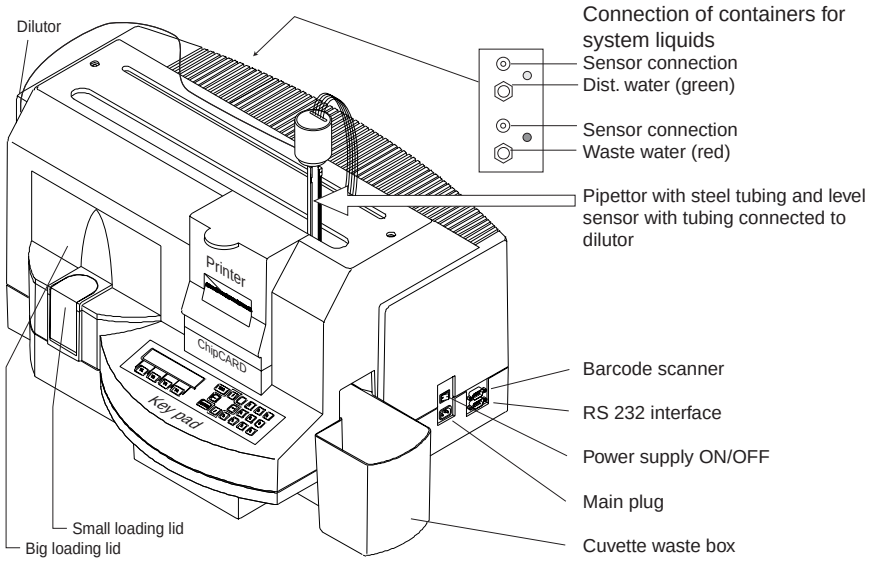


Figure 1 System Connections

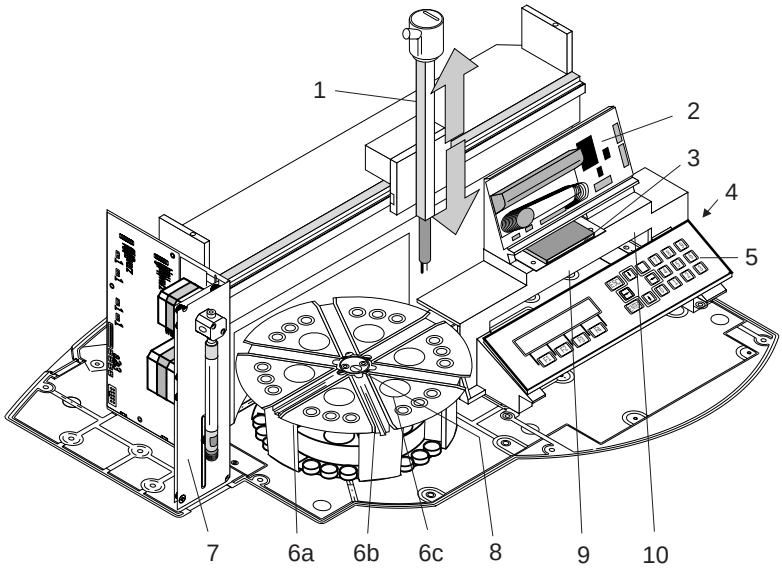


Figure 2 Modules

Item	Description
1.	37C temp. pipettor
2.	Thermal printer
3.	ChipCARD reader
4.	Cuvette waste box
5.	Keyboard
6a.	Sample rotor
6b.	Cuvette rail
6c.	Reagent position
7.	Dilutor
8.	Washing position for pipettor
9.	Incubation cell
10.	Measuring cells (6 parallel)

The sample rotor

The combined sample and reagent rotor consists of:

- 6 positions for the cuvette bars (6 cuvettes per bar).
- 6 numbered positions (R1 - R6) for the reagent vials.
  Two different vials can be used:
  - 4 ml plastic vial with **blue** adapter ring
  - 10 ml plastic vial with **white** adapter ring
- 1 reagent stirrer position on which all 6 reagent positions can be stirred just prior to sampling.
- 18 numbered sample positions
- rinsing station

Primary tubes

The following primary tubes can be selected in the Setup Menu under
< 1 Primary Tubes >:

- Sample cup
- 4.5 ml Beckton Dickinson Vacutainer (the short Vacutainer only)
- 3.0 ml Sarstedt Monovette

For further information refer to section 6.4.1 Define Primary Tubes.

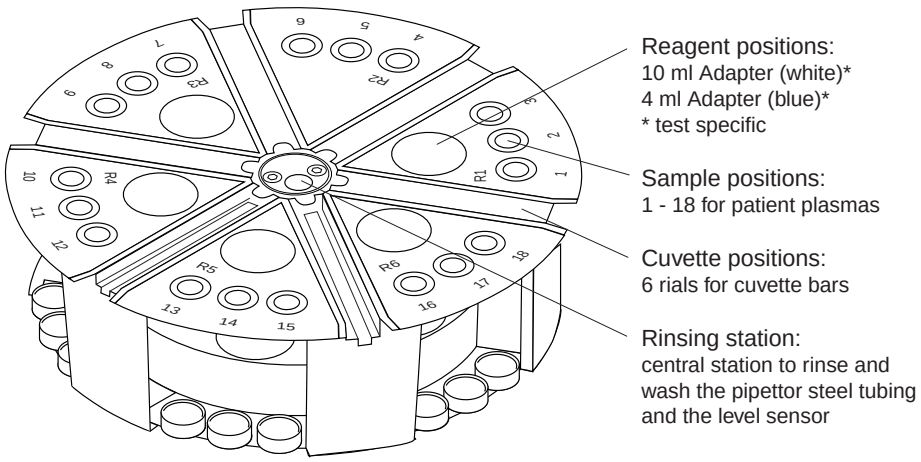

Reagent positions:
10 ml Adapter (white)*
4 ml Adapter (blue)*
* test specific
Sample positions:
1 - 18 for patient plasmas
Cuvette positions:
6 rials for cuvette bars
Rinsing station:
central station to rinse and wash the pipettor steel tubing and the level sensor

Figure 3 Sample rotor with positions

The cuvette bar

The cuvette bar has 6 wells. Up to 6 bars (36 cuvettes) can be loaded onto the sample rotor.

NOTE

To ensure correct loading, the cuvette bar is designed so that it can only be inserted one way (with semi-round opening inserted first), see picture. **Remove metal foil before using the cuvette bar.**

Each well of the bar contains a 1 x 3 mm stir bar. These stir bars are necessary to obtain accurate measurements.

Ensure that only the original cuvette bars and stir bars provided by the manufacturer are being use to operate the system otherwise the warranty may become null and void.

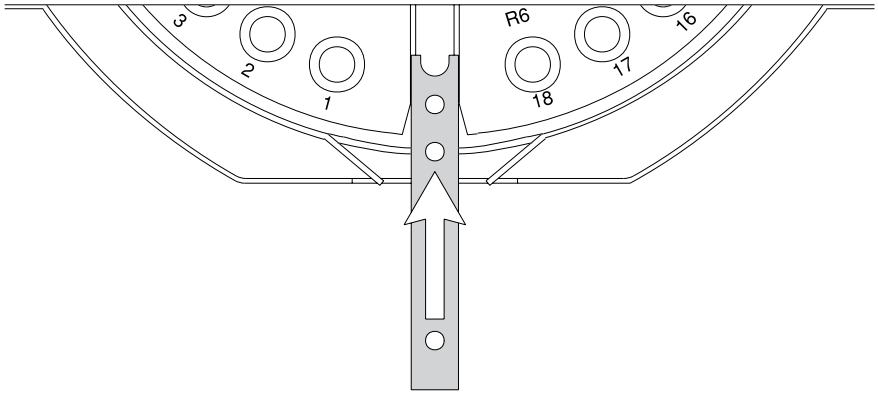


Figure 4 Bar with loading direction

The keyboard

The keys are used for direct control of the system and lead you through the operating software. The display informs you of the current operation mode of the system.

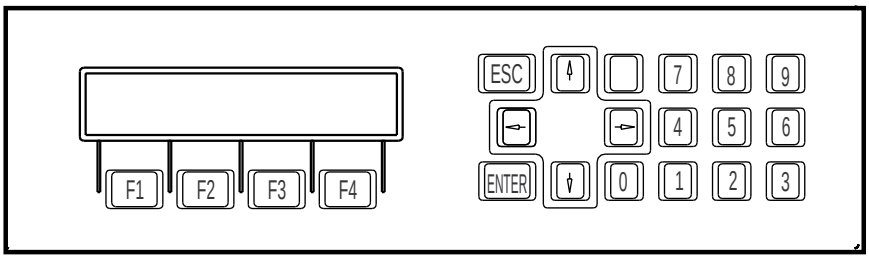


Figure 5 The keyboard

Keys	Meaning
Arrow Keys	Function key to scroll through the menu • The right arrow-key sets the decimal point. • The left arrow-key deletes single characters.
ESC-key	Function key to quit or confirm a certain menu point.
ENTER-key	Function key to confirm and save menu information.
Number-keys	Function keys to enter digits and enter or select special menu points.
Function keys (F1-F4)	Function keys to select certain operation steps which are displayed directly above.
Delete-key (blank)	Function key to delete Pat. ID or Lot-No completely or to be used as line feed key.

Mains connection fuses and power switch

The main connection fuses and power switch of the system are combined and integrated into the right side of the instrument. There is also a socket for a barcode scanner (optional) and for a connection to a host computer (optional) via an RS 232 C interface. The connections are marked accordingly.

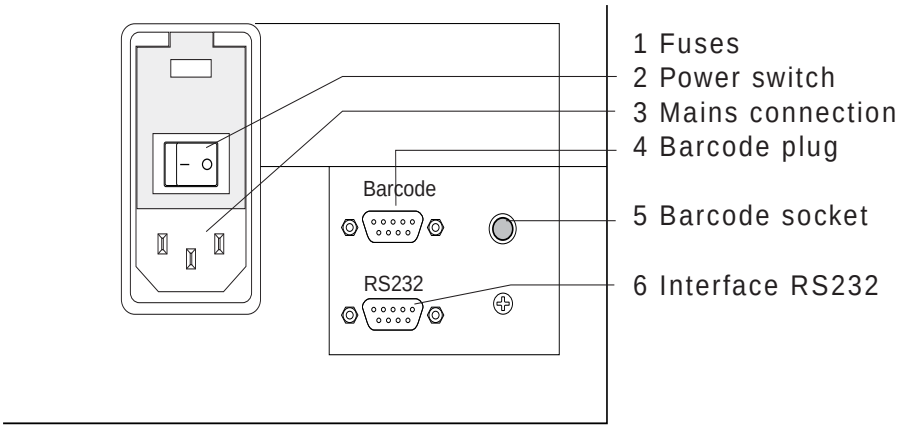


Figure 6 Power filter with mains plug

NOTE

The system is delivered without power supply cable. The cable must meet the local regulations. (e.g. IEC 320, VDE, CSA-C22.2, No. 21 and No. 49).

The cable has to be designed with NYLHY. The recommended length is 1.5 m, and the minimum cross section 3x 0.75 mm^2. A cold device plug is used at the system's end.

Use only fuses recommended by the manufacturer. Observe the instructions on the name plate located on the back side of the system. The analyzer is set to 230V by the manufacturer, change fuses (supplied in accessories) in power filter, if analyzer will be operated in 115V. See chapter 7.5 on changing fuses.

1.3 Measuring principle

The system operates according to the opto-mechanical measuring principle: It is well suited for lipemic and icteric samples as well as reagents with kaolin.

A light beam passes through the cuvette containing the test plasma onto a photo-detector. Any change in intensity of the transmitted light, that is light increase or decrease, is converted into an electric signal.

The period from adding the start reagent until clot formation is measured. It can be converted into the appropriate units then (%, Ratio, INR, mg/dl, g/l).

Once the start reagent has been added the measuring channel is repeatedly adjusted, that means the lamp intensity automatically adjusts to the turbidity of the test sample. In this process the turbidity of the sample plasma and the reagent are levelled out.

A stir bar in each cuvette provides homogeneity of the reagent-plasma medium during the measuring process. At the same time a small whirl emerges through the stir bar movement which assures that even the smallest fibrin clot is formed in front of the photo-detector.

This stirring action combined with the optical measurement, constitute the basic features of the patented „turbodensitometric measuring principle“.

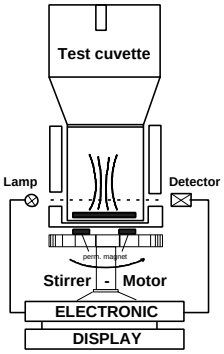


Figure 7 Measuring principle

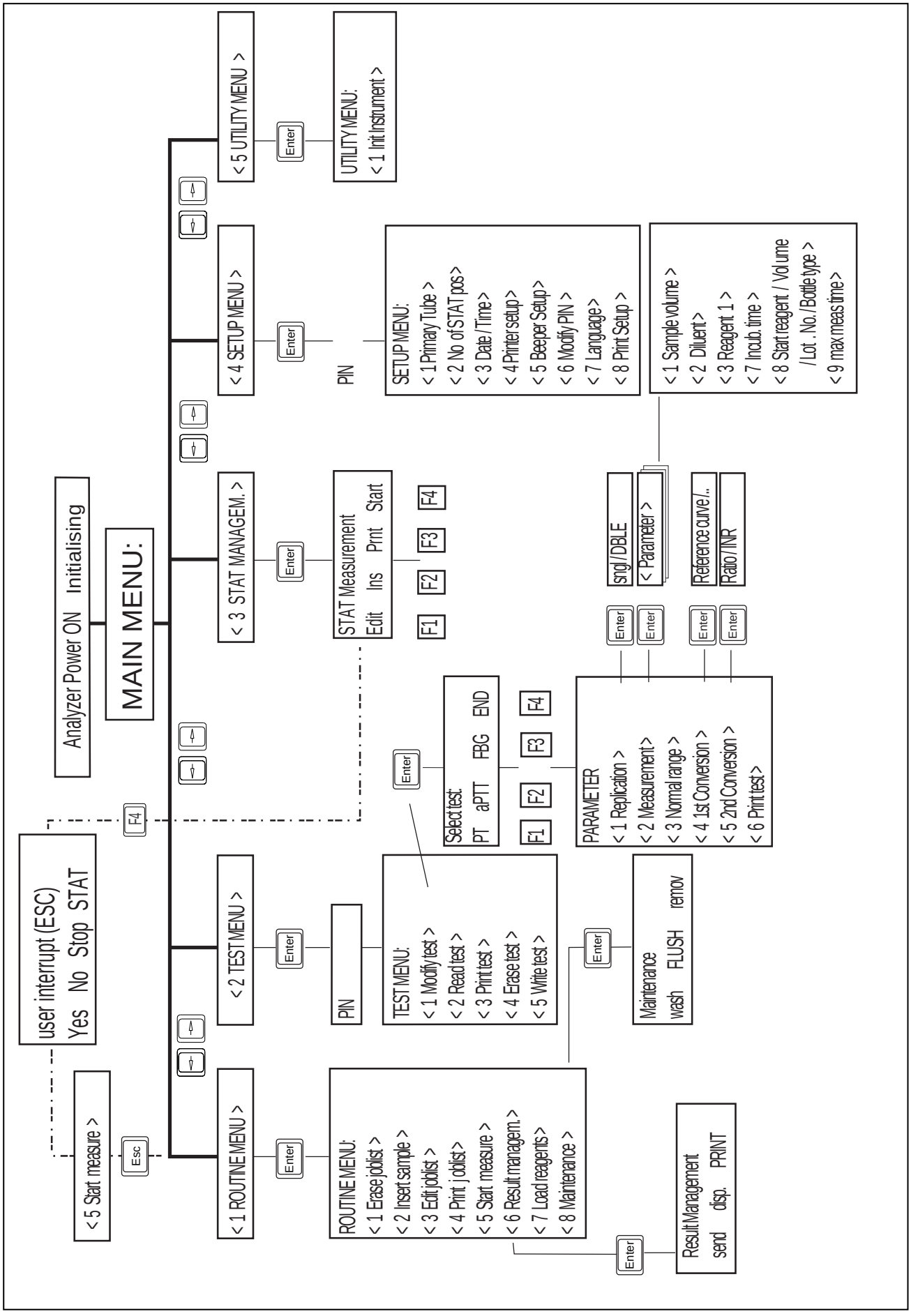
1.4 Software Overview

The software overview makes it easier to find the different functions desired. After the instrument has been switched on, it will initialize and automatically display the MAIN MENU.

```
MAIN MENU
< ROUTINE MENU >
```

By pressing the

- Arrow-keys right/left you can select a menu.
- ENTER-key opens a menu or selects a function.
- ESC-key steps back a level in the menu.


Analyzer Power ON Initialising
MAIN MENU:
user interrupt (ESC)
Yes No Stop STAT
< 5 Start measure >
Esc
< 1 ROUTINE MENU >
Enter
ROUTINE MENU:
< 1 Erase joblist >
< 2 Insert sample >
< 3 Edit joblist >
< 4 Print joblist >
< 5 Start measure >
< 6 Result managem. >
< 7 Load reagents >
< 8 Maintenance >
Enter
Result Management
send disp. PRINT
< 2 TEST MENU >
Enter
PIN
TEST MENU:
< 1 Modify test >
< 2 Read test >
< 3 Print test >
< 4 Erase test >
< 5 Write test >
Enter
Select test:
PT aPTT FBG END
F1 F2 F3 F4
Enter
Maintenance
wash FLUSH remov
F4
< 3 STAT MANAGEM. >
Enter
STAT Measurement
Edit Ins Prnt Start
F1 F2 F3 F4
< 4 SETUP MENU >
Enter
PIN
SETUP MENU:
< 1 Primary Tube >
< 2 No of STAT pos >
< 3 Date / Time >
< 4 Printer setup >
< 5 Beeper Setup >
< 6 Modify PIN >
< 7 Language >
< 8 Print Setup >
PARAMETER
< 1 Replication >
< 2 Measurement >
< 3 Normal range >
< 4 1st Conversion >
< 5 2nd Conversion >
< 6 Print test >
Enter
Enter
Enter
Enter
sngl / DBLE
< Parameter >
Reference curve /..
Ratio / INR
< 1 Sample volume >
< 2 Diluent >
< 3 Reagent 1 >
< 7 Incub. time >
< 8 Start reagent / Volume
/ Lot . No. / Bottle type >
< 9 max meas time >
< 5 UTILITY MENU >
Enter
UTILITY MENU:
< 1 Init Instrument >

2 Hazard and Precaution

This section contains the safety regulations that must be observed by all users of the system, to ensure safe and economic operation.

Importance of safety regulations

All safety instructions in this instruction manual must be observed to avoid damage to persons, property and the environment.

All local safety and environmental regulations and guidelines must also be observed.

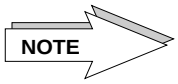
Disregarding of safety regulations

Disregarding these safety regulations or technical specifications may result in accidents with personnel or equipment, or environmental damages.

Hazards and Precautions

The system has been delivered by the manufacturer in a technically flawless condition. **In order to keep this condition the user must follow the following safety regulations of this manual.**

The system must be operated by skilled personnel only.



Note introduces rules to be observed.

Warning signals

Two different warning signals with different meanings are used in this section.

ATTENTION!

Potential danger may cause **minor injury or equipment damage,** if no precautions are taken.

WARNING!

Potential danger may cause severe **injury or death** if no precautions are taken.

Electrical safety:

WARNING!

Ensure that the **operating voltage** is set correctly before the instrument is connected to the main power supply.

Use only **grounded** sockets and extension cords when connecting the instrument to a power supply. Never disconnect grounding contacts.

Never disconnect the grounding contacts intentionally.
There is the risk of an electrical shock if
- The protective conductor is interrupted within or outside the device
- The grounded contact has been disconnected from the line.

Never remove protective guards or **secured components,** since you could expose electrically live parts. Even after the instrument has been switched off, some parts may contain voltage due to electrical charge.

All current carrying parts are sources of danger for an electrical shock.

Never use the instrument on a moist surfaces (floor, worktable or countertop), or place containers of liquids on top of the instrument. Liquids spilled into the instrument may cause an electrical shock.

Switch off the instrument and disconnect it from all power sources before performing maintenance or repair work. Perform only the maintenance/repair work described in this manual; unauthorized work on the instrument may cancel the warranty, and require expensive service work.

All work which requires the **instrument to be opened under voltage must only be carried out by a technician** who is familiar with the risks related thereto.

Use only **replacement fuses** of the stated type and with the stated minimum current;
- Never use ‘repaired’ fuses.
- Never short-circuit the fuse holder.

Fire and Explosion hazards:

WARNING!

Do not place the instrument near explosive mixtures of flammable gases, such as oxygen or hydrogen; electrical sparks could cause fire or explosions.

Mechanical Safety (system in operation)

WARNING!

Never remove housing parts while the instrument is on; moving parts such as the fan or motor drives may cause injury.

Always close the sample rotor-loading inlet during operation, to avoid contact with moving parts. **The probe will not stop when the loading inlet is open.**

Ensure that the pipettor does not stop over the sample rotor or the measuring block when the instrument is switched off.

- Use the protection cap for the pipettor if the system will not be operated for a long time, to avoid damage and contamination.
- Do not open covers during a run, to avoid damaging the pipettor.

If safe operation of the instrument is not possible switch the instrument off and secure it against use if:

- The instrument is damaged
- The instrument does not work properly
- The instrument has been stored / transported under adverse conditions
- The instrument has experienced severe temperature fluctuations

Samples, Reagents

WARNING!

Follow the instructions on the directional inserts for the correct use of reagents.

Avoid skin contact with samples and/or test reagents, as well as those instrument parts that touch samples and/or test reagents. **All instrument parts are potentially infectious, and reagents might irritate mucous membranes and the skin**. **All liquid and waste containers which carry sample and/or test reagents are marked with a biohazard symbol.**

If sample material is spilled onto the instrument, wipe it off immediately and decontaminate the affected surfaces.

Ensure that no foam or air bubbles are on the surface of reagents and sample material prior to loading the system: their presence could influence the measured results and the level detection of the needle. Ensure reagents are used at room temperature only.

Before using sample cups and reagent vials make sure to remove all covers/lids beforehand. Do not use organic solvents unless explicitly authorized by the manufacturer, as their use may result in damage to the cuvette bars, primary tubes, and waste water tubes.

Waste Liquids:

WARNING!

Dispose of waste liquids must be in compliance with applicable regulations.

Accuracy and Precision of Results:

WARNING!

Measure control samples and ensure the instrument is operating properly to obtain accurate results.

Inaccurate results may lead to a false diagnosis and endanger the patient.

User Qualification:

WARNING!

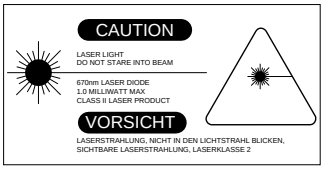
The system should be operated by trained personnel only.

Barcode Scanner:

ATTENTION:

Be careful when using the barcode scanner laser light.

- Avoid direct eye contact with the laser beam.
- Follow the manufacturer's instructions.
- Ensure the scanner was tested and authorized for use by the manufacturer.



Acoustic Signals

A beeper confirms all key strokes on the system keyboard. Thus, the user can recognise, for example, the end of a run, possible failures during operation, or the access to STAT mode without looking at the display.

3 Warranty

The representatives or authorised dealers warrant that the system does not have any material or manufacturing damages after installation if the instruction manual has been observed.

The warranty does not apply for damages which are caused
- By accidents, negligence, or non-observation of the instruction manual,
- By using inadmissible reagents or disposables, or
- By operating the instrument in an environment contradicting the specifications of this instruction manual.

Repair and service work must be carried out by technicians who have been authorised.

4 Service

The representatives or authorised dealers guarantee to carry out repair work during the official working hours from Monday to Friday with the exception of public holidays.

If you need service outside of that time contact our parent company or our authorised dealer.

5 Installation

This section describes how to unpack, install and prepare the instrument for use.

Safety regulations

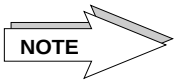
We assume that you have read chapter 2 Hazard and Precaution carefully.

5.1 Unpacking and installation of the system

5.1.1 How to prepare the installation area

Select a stable and level area for installation.
Ensure the power cable will reach the outlet without using any extension cords.

Ensure there is enough light for proper operation, but no direct sunlight.

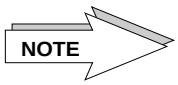


Do not put the analyzer on a shelf or on a roll-desk. Protect from direct sun light, significant temperature changes, humidity, and voltage variations.

Ensure the space above the system will be clear of equipment, supplies and shelves.

5.1.2 Check Contents

The instrument weighs about 35 pounds (17 kg), and can be carried or moved by one person. For the safety of the instrument and yourself, however, you should move the instrument using a rolling cart of have someone assist you.



Do not damage any packaging material, and keep them for possible later use, including the transport protection devices. Store them away from heat and humidity.

- Place box on the floor
- Remove all small parts from the box first, and ensure all accessories and disposables listed in section 8.5 have been received.

5.1.3 Unpacking the system

- Lift the system from the box (with assistant), and place on the installation area.

- Remove the left (1) and right (2) foam inserts and set aside (See figure 8).

Pay attention to the pipettor!
Be careful not to damage the pipettor, flat cable, steel tubing or level sensor; any damaged or defective parts must be replaced by a service technician before operating.

- Place the system in the correct position on the table.

- Remove all tapes and transport protection devices (see figure 9).

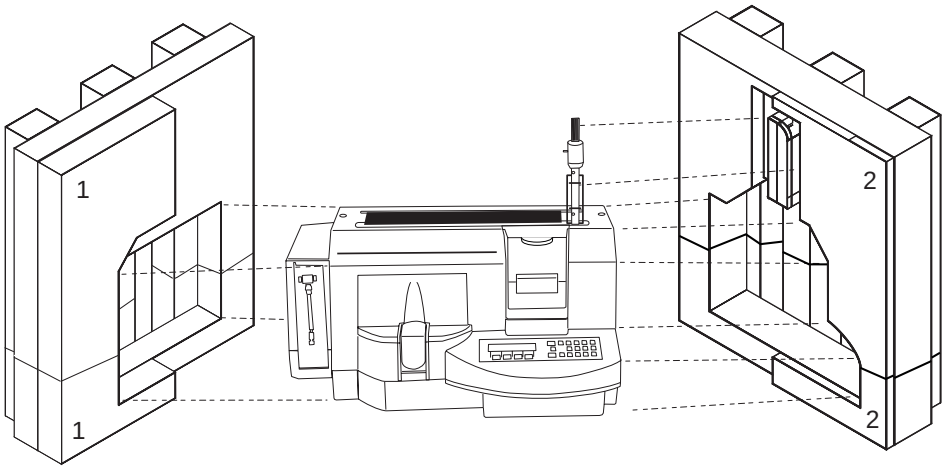


Figure 8 The system with foam inserts

Transport protection devices are:

See figure 9.

1. Box insert: protects the pipettor from moving in X-direction.

2. Plastic plate with cable ties: protects the pipettor from moving in Z-direction.

3. Red plastic screw on the steel tubing (top): protects from contamination.

4. Plastic protection cap on the steel tubing (bottom): protects from contamination.

5. Empty cuvette rack between sample rotor and measuring block.

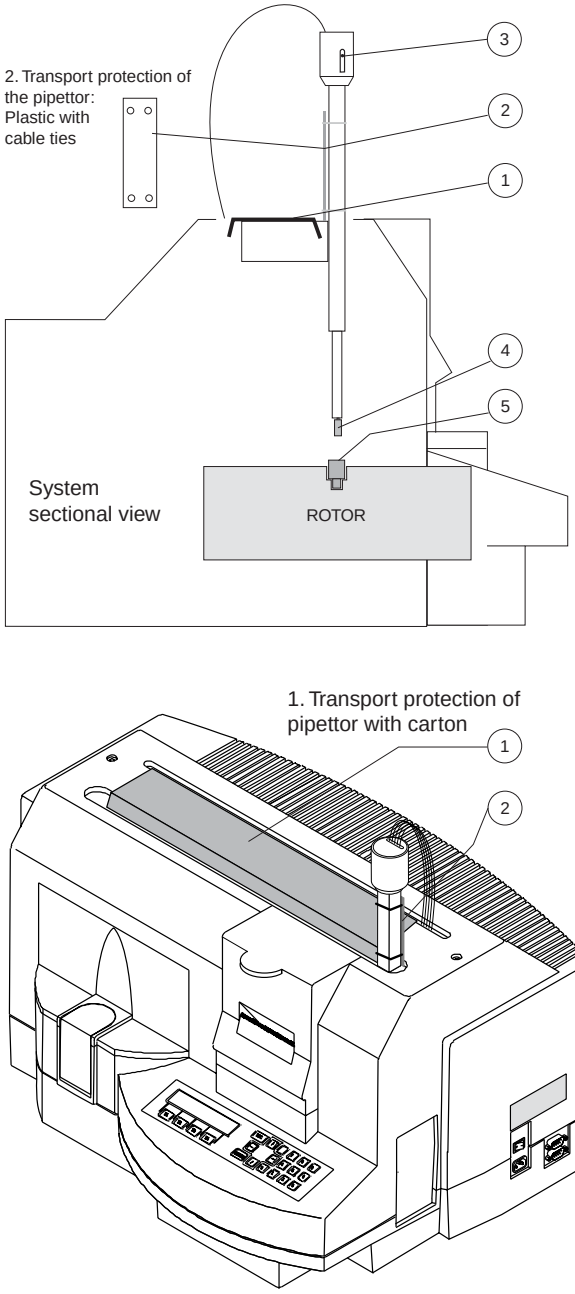


Figure 9 The system with transport protection devices

5.1.4 Assembly of the system

Before connecting the instrument to the main power supply, complete all instructions in this section.

5.1.4.1 Mount the diluter syringe and tubes

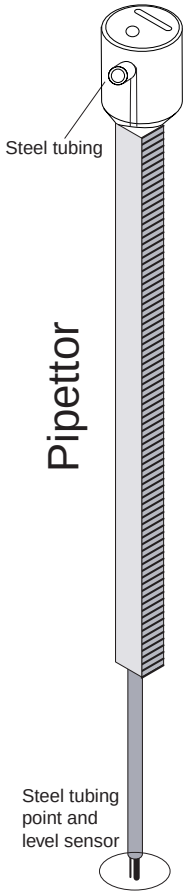
Mount the 250 µl dilutor syringe to the dilutor of the system according, see figure 10. When properly mounted, the syringe should not be wedged, and must be watertight.

- Press the syringe piston completely into the dilutor syringe.
- Open the locking screw.

- Push the syringe holder at the dilutor downward.
- Place the opening of the syringe piston onto the syringe holder of the dilutor.

- Screw the top of the syringe onto the adapter of the dilutor valve.
- Tighten the locking screw.

- Connect all tubing's to the dilutor valve.



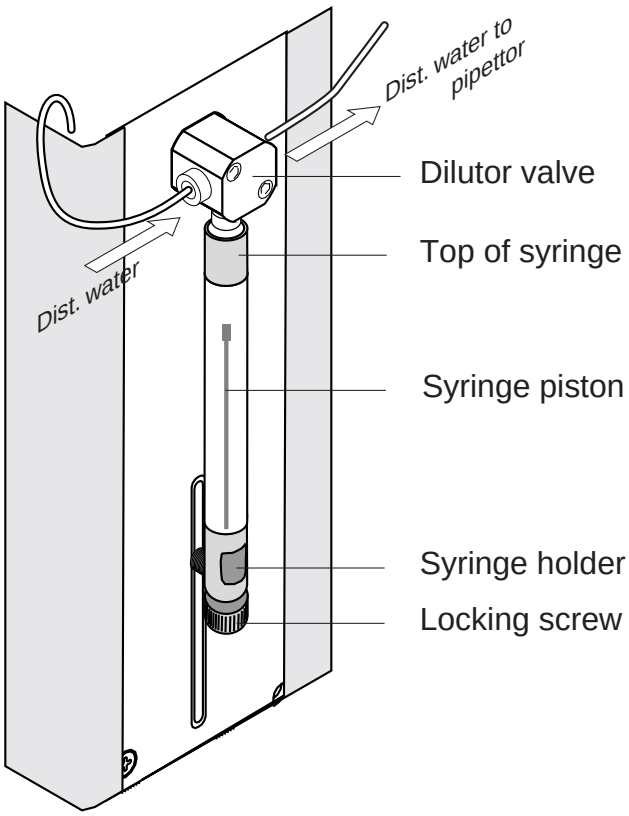


Figure 10 Diluter and syringe

Attach the tubes

The liquid system requires tubing between the diluter and pipettor. Connect the tube as follows:

- Take the tubing out of its plastic accessory bag.
- Remove the red plastic screw at the steel tubing of the pipettor.

- Screw the tubing (white screw) onto the diluter valve until hand-tight.
- Run the other end of the tubing through the tubing guides on the back of the instrument.

- Screw the end into the top of the arm (black screw). Make sure it fits properly and watertight.
- Review the entire tube path to ensure the tubes will be neither bent nor squeezed during instrument operation.

5.1.4.2 Connect the Liquid System Containers

- Place the distilled water container (with the green label) and the empty waste water container (with the red label) to the left rear of the system. Fill the distilled water container with at least 1 Liter of distilled water.
- Place the colour-coded sensors into the appropriate containers (green for dist. water, red for waste water). Ensure there are no air bubbles in the tubing of the distilled water container, or in the container itself.
- Plug the green and red colour-coded couplings into their matching sockets on the back of the system (see figure 11). A „click“ indicates the proper seating of the connectors.

The system will only function if the distilled and waste water tubes have been connected properly to the system.

NOTE

The system is switched OFF.

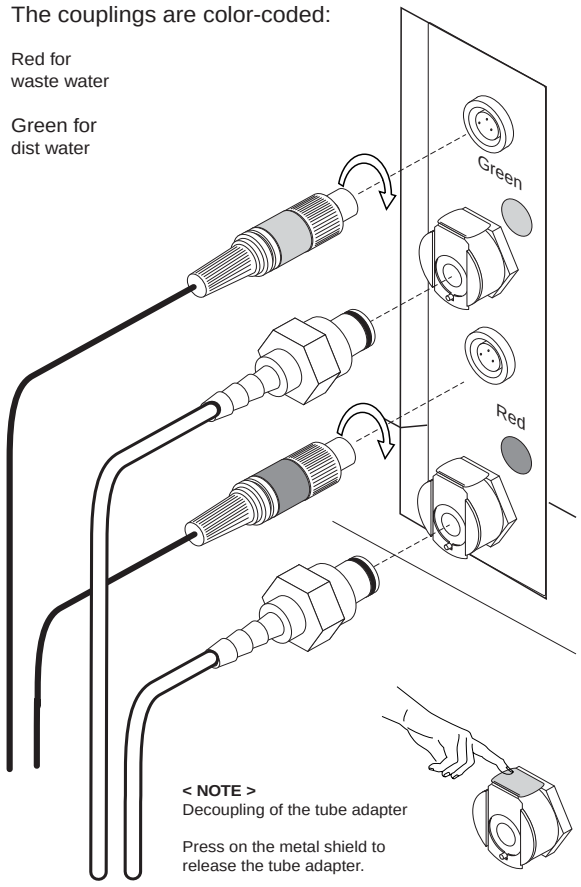


Figure 11 Connect the level sensor tubes to the system

NOTE

The distilled water container must have at least 1 Liter of distilled water. The waste water container should be emptied every day. Be careful not to have air bubbles in the distilled water container as well as in the tube.

Container

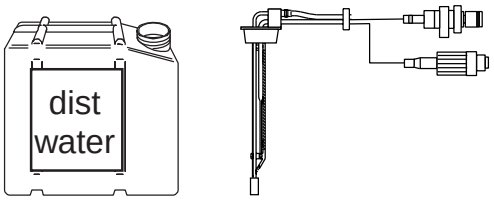


Figure 12 Container for distilled water. Container and tubes are coded with green.

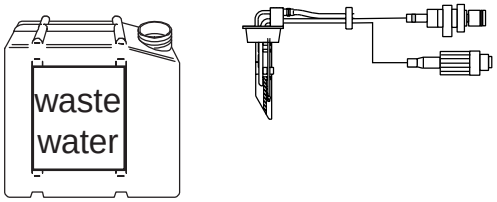


Figure 13 Container for waste water. Container and tubes are coded with red.

5.1.4.3 Connect the Barcode Scanner (Optional)

- Connect the optional barcode scanner to the system. Use the recommended type only.
- Connect the barcode scanner data cable to the upper socket (marked barcode) on the system (see figure 6).
- Plug the power supply into the socket next to it.

5.1.4.4 Connect a HOST or Personal Computer to the System

The system has an additional interface port (RS 232 C).The RS 232 interface is a uni-directional interface which allows the transfer of patient ID and results to a connected HOST or PC. Due to many different used HOST/LIS PC systems the interface protocol may vary, please ask your distributor or the manufacturer for further information on transfer of data's.

- Before switching on the computer, the PC must have been connected to the external periphery instruments. **Use the data cable recommended by manufacturer or dealer only.** Then connect the PC to the power supply. **Do not switch the computer on yet!**
  Now connect the data cable to the lower socket (marked RS 232) on the right side of the system and to the interface port of your computer.

NOTE

Before switching on the analyzer and before each re-initialisation, pay attention that all cuvettes and vials have been removed from the rotor and the measuring block.

- Now connect the system to the power supply. The ON/OFF switch is on the right side of the instrument.

- After complete installation the instrument and, possibly, the computer can be switched on and off accordingly.

See figure 6 Power ON/OFF, Power filter.

5.1.4.5 Insert and change printer paper

After switching on the system you can now insert the printer paper (see accessories). The printer paper can be inserted only when the system is switched on.

- Lift the printer cover above the keyboard and remove the previous paper roll holder, if necessary.
- Place the new paper roll with the paper roll holder into the correct position. The unrolling paper must run towards the **inside** of the printer

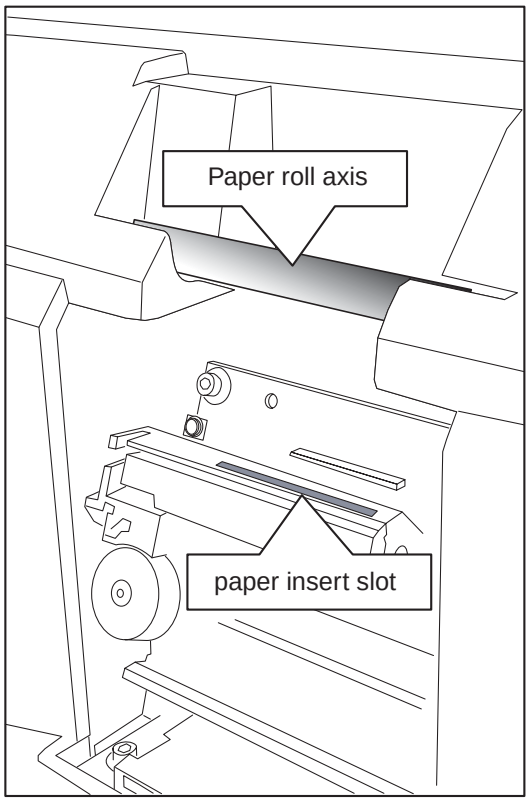


Figure 14 Printer housing

- Guide the paper - with a clear-cut end- into the paper slot of the printer. Once the paper has been captured it will be advanced automatically.
- Guide the paper through the slot of the printer cover and re-install the cover.

NOTE

Use manufacturer's printer paper only. Otherwise, the warranty may become void. Over time the text will fade. It is recommended that all printouts be copied for storage purposes.

5.1.4.6 Mount the cuvette waste box

The cuvette waste box must be attached before using the instrument. The cuvette bars which are automatically ejected from the measuring unit will be collected.

Be careful that plasma as well as reagents can flow out from the cuvette bars.

Therefore it is necessary to clean the box in regular intervals.

Mounting the waste box

See figure 15 next page

- Take the waste box out of the accessory box.
- As shown in the figure, press the box gently.
- Guide the waste box, gently pressed and slightly tipped, into the housing space so that the locking devices on the inside prevent the box from slipping.

NOTE

Use caution, as the cuvette bars that are collected in the waste box, may leak plasma and reagents.

If mounted properly the nose of the waste box will be placed under the measuring block and will collect used cuvette bars. It is recommended to clean the waste box weekly using a 10% bleach solution.

Demounting the waste box

- Remove the box by pressing it gently and slightly tipping it.
- Dispose of the cuvette bars in compliance with biohazard regulations. •

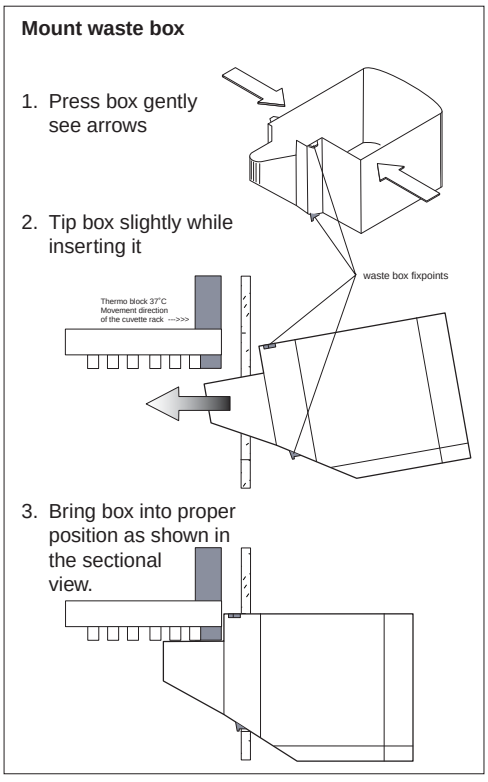
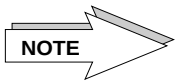

Mount waste box
1. Press box gently see arrows
2. Tip box slightly while inserting it
waste box fixpoints
Thermo block 37°C
Movement direction of the cuvette rack --->>>
3. Bring box into proper position as shown in the sectional view.

Figure 15 mounting the cuvette waste box

5.2 Instrument control Card (ICC)

The manufacturer recommends to fill in the Instrument Control Card (see attachment) of each system after its initial installation and to return it to the manufacturer within four weeks. With this Instrument Control Card the manufacturer will register your system. The customer confirms proper receipt, functioning and completeness of the delivered system.



The Instrument Control Card is the basis for any warranty claims.

Possible claims can only be called for if the Instrument Control Card had been returned to the manufacturer after the initial installation of the system.

The document is enclosed.

5.3 Language Setup

The analyzer is pre-set to the English language.
If you want to change the language follow section 6.4.7 Language.

6 Operation

This section describes how to routinely operate the system as well as information on quality control of coagulation measurements. Furthermore you will find hints to possible failures and troubleshooting.

Training

Onsite training courses are offered for this instrument. For additional information contact your distributor.

Safety precautions

Thoroughly review the Hazard and Precautions section of this manual before proceeding.

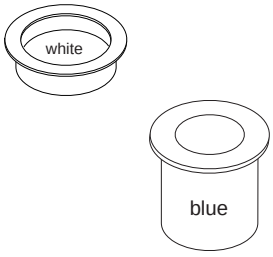
6.1 Routine Operation <1 ROUTINE MENU>

The system will be ready for coagulation analysis after initial set-up has been completed, see section 6.4 General Setting (SETUP MENU). The following descriptions explain the ROUTINE MENU and give an insight into safe coagulation analysis.

In the ROUTINE MENU you can select between three different methods. You can use nearly all well-known PT / aPTT and Fibrinogen reagents on the system. Please note that due to the large variety of coagulation reagents on today's markets only a certain number of reagents have been checked and adjusted to the system. See section 8.7 Adaptation of coagulation reagents for further information.

Preparing routine operation

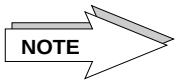
- The instrument is connected to the power supply.
- The distilled water container is filled with water (without bubbles) and connected to the system.
- The waste water container is empty and connected to the system.
- The waste box is cleared of cuvette bars.
- All tubes have been properly connected, and are neither squeezed nor bent.
- Sufficient printer paper has been inserted.
- The liquid system is filled and without bubbles.



Reagents for the tests will be reconstituted according to the package insert and will be filled into the reagent vials. The delivered reagent vials have the following dead volumes:

10 ml reagent vial (white adapter)	without stir bar with stir bar	dead volume: 1.5 ml dead volume: 2.0 ml
4 ml reagent vial (blue adapter)	without stir bar with stir bar	dead volume: 0.5 ml dead volume: 0.8 ml

6.1.1 Switch ON the system



The instrument must be free of cuvette bars, sample and reagent vials.

- Switch the instrument on by setting the power switch to the position **I = ON**.

The display shows the instrument name and checks all internal modules automatically (the pipettor moves to the washing station).

```
Diverse displays ...
```

User dialogue display of the system

Then all system modules will be initialised.

The following data will be printed:

```
C2820501 V1.04 04/22/02
07.05.2002          08:55
```

Ser. No. / SW-Version / Release
Date / Time

The instrument is ready for operation.

- Use the arrow keys (</>) to select <1 ROUTINE MENU> in the MAIN MENU.

```
MAIN MENU:
< 1 ROUTINE MENU >
```

- Press the **ENTER**-key to confirm.

The following display appears:

```
MAIN MENU:
< 1 Erase joblist >
```

6.1.2 Rinsing with distilled water

For transport protection reasons the system has been delivered in dry condition, without any liquids. Before measuring with the system it is necessary to perform a rinsing process and fill all system modules with liquid (pumps, dilutor and tubing's). This procedure also removes any air bubbles from the tubing system and the dilutor tubing. You can now check whether all tube and screw connections have been installed properly. Should you notice any leaking, tighten the connections to the point that they are watertight.

- Use the arrow keys (</>) to select < 8 Maintenance > in the ROUTINE MENU.

```
ROUTINE MENU:
< 8 Maintenance >
```

- Press **ENTER** to confirm and rinse the pipetting system of the system.

The following display appears:

```
Maintenance
wash FLUSH     remov
```

F1 F2 F3 F4 = accompanying function keys

• Press function key **F2**.

The instrument will rinse the system with distilled water. After the initial installation this procedure should be repeated until all tubes are filled with liquid completely.

By Pressing **F4 = remov** cuvette bars will be ejected into the waste box.

During rinsing the following display appears:

```
Maintenance
```

```
Maintenance
wash FLUSH     remov
```

• Leave the menu after rinsing by pressing **ESC**.

The following display appears:

```
ROUTINE MENU:
< 8 Maintenance >
```

Pressing **ESC** will take you back to the MAIN MENU.

After this procedure the instrument pipetting system has been rinsed with distilled water. The manufacturer recommends repeating this procedure after the initial installation several times to secure that no air bubbles are in the pipetting tube and that no liquids containing thrombin, for example, will remain in the liquid system (if system has already been used). Check the system for leakage's again and re-mount, if necessary, all connections and tubes before repeating the rinsing cycle.

6.1.3 Disinfection of waste tubing (Terralin), change of FW-Filter

It is necessary to disinfect and clean the liquid system, tubing's at regular intervals, see section 8.1 Maintenance and Hygiene to avoid reagent or sample residues, possibly causing inaccurate results or improper functioning of the analyzer. Therefore, regular disinfection and cleaning cycles must be run to guarantee proper functioning of the system.

Follow the instructions for disinfection of the system tubing's:

Clean the distilled water container and change filter

1. Remove the **Distilled Water Sensor** (green mark) from the **Distilled Water Container.**

2. Remove the white **fresh water filter** from the end of the Distilled Water Sensor and replace it with a **new fresh water filter**.

3. Empty the **Distilled Water Container** and clean the inside using a **70% alcohol solution**.

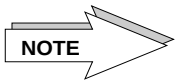
4. Rinse the **Distilled Water Container** thoroughly with distilled water to remove any traces of the alcohol solution.

5. Refill the **Distilled Water Container** and return the **Distilled Water Sensor** to the container.

Disinfection of Wash Station and Waste tubing with Cleaning Solution

6. Make a working solution of Cleaning Solution. Fill 2 Liters of distilled water into the **Cleaning Solution Container** (white label) and add 20 ml of concentrated Cleaning Solution. Swirl gently.

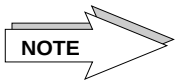
7. Place the **Waste Water Container** carrying the **Waste Level Sensor** (red label, sensor) beside or behind the analyzer on the same height level. The container **may not be** placed underneath the analyzer. Make sure the waste tubing (red marked) and the electrical plug of the waste tubing are correctly connected to the fluid panel of the back side of the analyzer.



Do not disconnect any of the level sensor tubing's (red/green) and electrical plugs at the fluid panel at the back side of the analyzer.

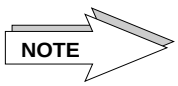
8. Take out **4ml** of the diluted working **Cleaning Solution** from the **Cleaning Container** using a standard commercial pipette, e.g. Eppendorf.

9. Guide the pipette over the Wash Station, located in the center of the reagent and sample rotor.



Make sure that neither the steel needle nor the level sensor of the probe will be damaged or bent during this operation. The system may not be in operation, moving.

10. Dispense the diluted **Cleaning Solution** out of the pipette into the wash station. Repeat this process until you have added 4ml into the Wash Station. Leave the working **Cleaning Solution** in the Wash Station for at least **2 min**.



Make sure the Cleaning Solution inside the Wash Station remains on the same level. It may not disappear inside the Wash Station. In this event place the Waste Water Container on a higher level, meaning above the height of the wash station of the analyzer and repeat adding the Cleaning Solution into the Wash Station. Further make certain not to overflow the wash station to avoid any liquid flowing into the sample/reagent rotor.

Flush after cleaning

After the disinfection/cleaning cycle with Cleaning Solution it is absolutely necessary to rinse the liquid system with distilled water to ensure that no Cleaning Solution may remain in the liquid system at all.

Follow the instructions to rinse the system with distilled water:

11. Make sure the **Distilled Water Sensor** is equipped with a **NEW fresh water filter** and the **Distilled Water Sensor** is placed correctly in the **Distilled Water Container**.

12. Run flush cycles with distilled water described as follows:

- Use the arrow keys (</>) to select <5 UTILITY MENU> in the MAIN MENU.

```
MAIN MENU
< 5 UTILITY MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
 UTILITY MENU
 <1 Init Instrument>
```

- Press **ENTER** to confirm the message.

The following display appears:

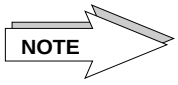
```
Init Instrument
Init ... (ESC=Stop)
```

The motors and the diluter will be initialised. During this phase the cuvette racks in the measuring block will be moved one position to the right and will be ejected from the measuring block.

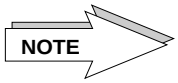
The following display appears:

```
Init Instrument
Flush... (ESC=Stop)
```

Then the liquid system will be initialised. Liquids are pumped into the tubing's. Press **ESC** if you want to finish initialisation.



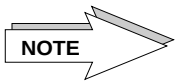
This flush process should run a minimum 5-8 minutes or until no foam residues of Cleaning Solution will remain in the liquid system, waste tubing (red marked). Check if waste water runs through the waste tubing into the Waste Water Container and no foam remains in the waste tubing.



The manufacturer recommends repeating this procedure at least twice a month. Once a year it is recommended to renew all liquid containing parts of the system. Ask your local dealer or the manufacturer for available maintenance/service kits.

6.1.4 Rinsing with Washing Solution

In the ROUTINE MENU you can choose to clean the pipetting system of the instrument with an extra Washing Solution. This is especially recommended after the use of reagents containing thrombin, such as Fibrinogen. The system disposes of an automatically wash cycle if Thrombin containing reagents, e.g. Fibrinogen are being used. Once the reagents are introduced, see section 6.1.5 and are requested to run in a joblist, section 6.1.7 the system automatically washes the system with washing solution after the use of such thrombin containing reagents.



This intensive washing cycle must be run daily after routine work in order to avoid any residues of previous measurements.

Follow the instructions to wash the system:

- Use the arrow keys (</>) to select < 8 Maintenance > in the ROUTINE MENU.

```
ROUTINE MENU
< 8 Maintenance >
```

- Press **ENTER** to confirm.

The following display appears:

```
Maintenance
WASH flush     remov
  F1   F2   F3   F4
```

- Press **F1= WASH** and follow the instructions of the display.

The following display appears:

```
1: washer:
LOAD 3.0ml      skip
  F1   F2   F3   F4
```

If no washing solution has been loaded the following display appears. Put the white adapter ring into reagent position 1: = R1 extended automatically and put the 10 ml reagent vial filled with min. 3 ml Washing Solution into the reagent position. Confirm either with **F1= Load** or with **ENTER**.

```
Maintenance
```

To cancel this procedure press **F4= skip**. After having confirmed with **F1** or **ENTER** the analyzer will start an automatic wash cycle to clean the tubing's (consumption per wash cycle ca. 110 µl).

The next display appears:

```
Maintenance
WASH flush     remov
```

- Press **ESC** to leave the menu.

The following display appears:

```
ROUTINE MENU
< 8 Maintenance >
```

The system has now been cleaned with Washing Solution. If necessary, this procedure can be repeated. Press **ESC** to get back to the upper menu level.

6.1.5 Loading and unloading reagents

Before entering a joblist it is possible to load and later unload reagents for daily routine. Observe the following preconditions:

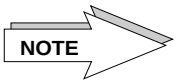
- All reagents must be reconstituted according to the package insert.

- The system is preset to the supplied reagent vial types. To avoid inaccurate level detection you should use the reagent vials with the adapter rings only. Make sure that only predefined reagent vial types (4 ml or 10 ml) are positioned in the sample or reagent rotor. For definition of reagent vial types see section 6.2.2 Enter Method Parameter for definition of reagent vial types.

10 ml reagent vial (white adapter)	without stir bar with stir bar	dead volume: 1.5 ml dead volume: 2.0 ml
4 ml reagent vial (blue adapter)	without stir bar with stir bar	dead volume: 0.5 ml dead volume: 0.8 ml

The dead volumes mentioned above have been considered when the volume is asked for.

Loading PT, aPTT and Fibrinogen reagent is described in the following example.



Remember to use the provided adapter rings (4 ml vial = blue ring; 10ml vial = white ring). Always position the reagent vials with the adapter rings into the correct reagent position in the sample rotor and make sure to use predefined reagent vial types only to avoid inaccurate level detection.

The system has an automatic reagent stir position in order to avoid sedimentation's. If reagents are stirred, Teflon stir bars must be put into the reagent vials. To select reagent vial types, see section 6.2.2 Enter Method Parameter.

• Use the arrow keys (</>) to select <7 Load reagents> in ROUTINE MENU.

```
ROUTINE MENU
< 7 Load reagents >
```

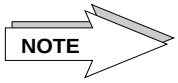
• Press **ENTER** to confirm.

The following display appears:

```
1: washer:
LOAD          unload
 F1             F4
```

The reagent position for the Washing Solution will be extended automatically. Should you have loaded Washing Solution already, the above display appears.

- Press **F1** to confirm loading.



By pressing F4 'remove' you inform the system that you have removed reagent and/or washing solution from the sample rotor. 'Remove' will always be displayed if you have loaded the sample rotor with reagents and/or washing solution beforehand. Once the sample rotor has been loaded with reagents and/or washing solution 'remove' will be displayed to 'unload' the sample rotor.

If 'skip' is displayed instead of 'remove' you can press F4 to skip over loading with reagent and/or Washing Solution. Remember however, that the analyzer cannot run measurements or start cleaning cycles if reagents and/or Washing Solution have not been loaded. This message will always be displayed when no reagents and/or Washing Solution have been loaded to the sample rotor.

The following display appears:

```
2: Buffer:   9999992
LOAD            skip
```

The sample rotor position will be extended automatically. Load the sample rotor with Buffer in position 2: = R2 and confirm with **F1**.

If you want to skip over this position and not load Buffer press **F4**.

The following display appears:

```
3: FBG          8888
LOAD            skip
```

The sample rotor position will be extended automatically. Load the sample rotor with Fibrinogen reagent in position 3: = R3 and confirm with **F1**.

If you want to skip over this position and not load Fibrinogen press **F4**.

The following display appears:

```
4: CaCl2       88888
LOAD            skip
```

The sample rotor position will be extended automatically. Load the sample rotor with Calcium Chloride in position 4: = R4 and confirm with **F1**.

If you want to skip over this position and not load Calcium Chloride press **F4**.

The following display appears:

```
5: aPTT     99999995
LOAD            skip
```

The sample rotor position will be extended automatically. Load the sample rotor with aPTT reagent in position 5: = R5 and confirm with **F1**.

If you want to skip over this position and not load aPTT reagent press **F4**.

The following display appears:

```
6: PT          88888
LOAD            skip
```

The sample rotor position will be extended automatically. Load the sample rotor with PT reagent in position 6: = R6 and confirm with **F1**.

If you want to skip over this position and not load PT reagent press **F4**.

After all reagents have been positioned on the sample rotor the following display appears.

```
ROUTINE MENU
< 7 Load reagents >
```

- Press **ESC** to get back into the MAIN MENU.

6.1.6 Delete joblist, delete samples

If you want to delete a joblist from the memory follow the instructions:

- Use the arrow keys (</>) to select <1 Erase joblist > in the ROUTINE MENU.

The following display appears:

```
ROUTINE MENU
< 1 Erase joblist >
```

Press **ENTER** to confirm.

The following display appears:

```
Really erase joblist?
YES   no
```

If you want to delete the joblist confirm with **F1 = YES**. If you do not want to delete it, press **F2 = NO**. Confirm with **F1**.

The following display appears:

```
Remove samples 1-9
and close cover
```

- Remove primary tubes 1 to 9 from the sample positions extended automatically and confirm with **ENTER**.

If more than 9 primary tubes are in the sample rotor the following message appears:

```
Remove samples 10-
and close cover
```

• Remove the remaining primary tubes 10 - 18 and confirm with **ENTER**.

The following display appears:

```
ROUTINE MENU
< 1 Erase joblist >
```

• Press **ESC** to get back into the MAIN MENU.

6.1.7 Enter a new joblist

Before entering a joblist you must define whether single or double determinations shall be made, see section 6.2.2.1

The following examples show how a joblist is to be entered:

Example 1:		
01 = Sample 1	**S-ID: 30001** = consecutive no.	**PT and APTT** = test to be measured
Example 2:		
02 = Sample 2	**S-ID: 30002** = consecutive no	**PT, APTT, FBG** = test to be measured
Example 3:		
03 = Sample 3	**S-ID: 123** = individual no	**PT** = test to be measured

Example 1:

• Use the arrow keys (</>) to select < 2 Insert sample > in the ROUTINE MENU.

```
ROUTINE MENU
< 2 Insert sample >
```

• Press **ENTER** to confirm.

The following display appears:

```
01 S-ID: 30001
pt   aptt  fbg   all
F1    F2    F3    F4
```

The sample rotor will automatically advance to the position to be loaded with sample 1 (01 S-ID:). Load the sample rotor with the first primary tube and select the tests with keys **F1-F4**. In this case the tests **pt=F1** and **aptt=F2** have been selected.

The following display appears:

```
01 S-ID: 30001
pt   APTT  fbg   all
```

After the tests have been selected they will appear in capital letters.

• Press **ENTER** to confirm.

The following display appears:

Example 2

```
02 S-ID: 30002
pt   aptt  fbg   all
```

The sample rotor will automatically advance to the position to be loaded with sample 2 (02 S-ID:). Load the sample rotor with the second primary tube and select the tests with keys **F1-F4**. In this case the tests pt, aptt and fbg have been selected, i.e. **all = F4**.

• Press **ENTER** to confirm.

The following display appears:

Example 3

```
03 S-ID: 123
pt   aptt  fbg   all
```

The sample rotor will automatically advance to the position to be loaded with sample 3 (03 S-ID:). Load the sample rotor with the third primary tube and select the tests with keys **F1-F4**. In this case the test **pt=F1** has been selected. If you want to change the patient ID press the left arrow key (<) until the patient ID is no longer displayed. You can now enter the individual ID, here **123**.

• Press **ENTER** to confirm.

The following display appears:

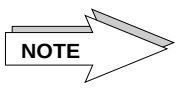
```
04 S-ID: 30003
pt   aptt  fbg   all
```

The sample rotor will extend automatically the position to be loaded with sample 4 (04 S-ID:). Repeat this procedure to insert more patient ID´s. Press **ESC** to leave this Menu.

The analyzer offers two possibilities to enter patient ID's. If no ID is entered the system will automatically assign consecutive numbers.

1.) Enter the patient ID manually. Using the number keys (0-9), enter the patient ID up to 10 digits.

2) Enter the patient ID by using the barcode scanner. Press the button on the barcode scanner and direct the scanner window to the barcode label of the **primary tube**. Continue pressing the button until a **beep** confirms entry of ID.



A large number of barcodes can be used. If the system does not accept a certain barcode contact the manufacturer or enter the patient ID manually.

Press **ESC** to leave the Menu.

The following display appears:

```
ROUTINE MENU
< 2 Insert sample >
```

The sample rotor has a maximum of 18 sample positions of which 15 can be used for routine work. Up to 3 positions can be used for STAT measurements. To load the sample positions repeat the procedures as described in this chapter.

Press **ESC** to get back to the MAIN MENU.

6.1.8 Handle the joblist

After entering the joblist into the memory, entries may be reviewed for accuracy or modification.

• Use the arrow keys (</>) to select <3 Edit joblist> in the ROUTINE MENU.

```
ROUTINE MENU
< 3 Edit joblist >
```

• Press **ENTER** to confirm.

The following display appears:

```
01 S-ID: 30001
PT   APTT   fbg   all
```

The desired test of each sample is displayed in capital letters. All other tests will be displayed in lowercase. By pressing the function keys **F1-F4**, tests may be selected or deselected or further tests can be added.

With the **up** and **down** arrow keys you can select the next sample.

• Press **ESC** to leave this menu point.

The following display appears:

```
ROUTINE MENU
< 3 Edit joblist >
```

• Press **ESC** to get back to the MAIN MENU.

6.1.9 Print of a joblist

The description how to print a joblist follows in this section. The printed joblist will provide an overview of the patient samples and methods.

• Use the arrow keys (</>) to select <4 Print joblist> in the ROUTINE MENU.

```
ROUTINE MENU
< 4 Print joblist >
```

• Press **ENTER** to confirm.

The following display appears:

```
printing joblist
```

The joblist will be printed on the internal printer. After printing this function will re-appear.

```
ROUTINE MENU
< 4 Print joblist >
```

• Press **ESC** to get back to the MAIN MENU.

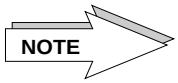
Example of printed joblist.

```
C2820501 V1.04 04/22/02
07.05.2002        08:44
ROUTINE Joblist:
T1  =  PT PT
T2  =  APTT APTT
T3  =  FBG Fibrinogen

No  Sample-ID  T1 T2 T3
1:  30001      x  x
2:  30002      x  x  x
3:  123        x

----------------------------------------
```

- Test name (short form)
- selected tests



Have the joblist printed after entry. Thus you can control whether it contains all selected entries. See chapter 6.1.8 Handle the joblist if you want to modify anything.

6.1.10 Start measuring, load cuvette bars

After printing the joblist start measurement. Follow the instructions in this section to run measurements.

• Use the arrow keys (</>) to select <5 Start measure> in the ROUTINE MENU.

```
ROUTINE MENU
< 5 Start measure >
```

• Press **ENTER** to confirm.

The following display appears:

```
Select test:
PT   aPTT   FBG   all
```

With the function keys **F1-F3** below the display a single test will be run. With the function key **F4 = all,** all three tests will be run automatically (RANDOM ACCESS).

Example: PT = F1

The following display appears:

```
Prepare measure
```

The following display appears:

```
INFO
check waste box
```

The message ‘check waste box’ is displayed for a short moment every time you enter a new joblist. Empty the waste box if used cuvette bars are still in.

The following message will be displayed:

```
Insert cuvette-bar
and close cover
```

The system will calculate according to the joblist how many cuvette bars are needed. The sample rotor automatically advances to the next position for a cuvette bar. Place the cuvette bar properly into its position.

This procedure will be repeated until all bars for the measurements have been positioned.

• Press **ENTER** to confirm.

If no reagents are loaded the sample rotor will automatically advance to the reagent position. Place the adapter ring and the **predefined** reagent vial of the selected test (here **PT**) into it. See section, 6.2.2 Enter Method Parameter.

The display will show the reagent volume necessary for the tests.

```
6: PT      123456789
LOAD 2.4ml      skip
```

The displayed figure already considers the necessary dead volume of the reagent vial.

Dead volumes:

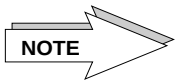
10 ml reagent vial (white adapter)	without stir bar with stir bar	dead volume: 1.5 ml dead volume: 2.0 ml
4 ml reagent vial (blue adapter)	without stir bar with stir bar	dead volume: 0.5 ml dead volume: 0.8 ml

Having positioned the reagent vial with adapter into the sample rotor you can confirm this in two ways:

F1 (load) or = ENTER	The reagent has been loaded and the entry is confirmed.

F4 (skip) = The reagent has not been loaded, the entry was not confirmed.

- In this case press **F1** or **ENTER** to confirm.



Remember that the supplied reagent vials consider sufficient dead volume when calculating the reagent volume. Therefore the reagent volumes are larger than what is actually needed for the tests. Always use the adapter rings and the pre-defined reagent vials as the volume calculation of the reagent will be influenced negatively otherwise.

The instrument will check the reagents for sufficient volume. If reagents are missing or the volume is insufficient the following display will appear:

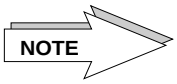
For example:

```
6: PT      123456789
only x.xml of  x.xml
```

Load the missing or insufficient reagent in position R6. Remember the necessary dead volume.

- Press **ENTER** to confirm end of loading.

If you do not want to load the missing reagents press **ESC**. The analyzer will measure as many samples as possible with the available reagents. Samples not measured will be identified with a note on the printout.



By pressing ESC and thus refuse to load the missing reagents, not all measurements will be worked off your joblist. The system will do all measurements possible with the reagent volume. Follow the steps in this section to work off the remaining measurements.

The following display appears:

```
Pipettor     M-Block
 37.4          38.4
```

The message Pipettor / M-Block indicates the temperature of the measuring block and the pipettor. This message will be displayed until the correct temperature has been reached.

The following display appears:

```
4 PT Samples       <
No Results available
```

The system will start measurements. The number (e.g. 4 PT samples) of measurements for each method will be displayed. The results will automatically be printed on the internal printer.

The display will show ‘no results available’.

The rotating symbol (<) in the upper right hand corner of the display means that the instrument is measuring presently.

At the completion of all tests a short beep will be heard and the following message appears on the display:

```
STATE
Normal Termination
```

All cuvette bars that were not completely used will remain in the measuring block, and be used in the next testing cycle.

Example of a printed result:

```
C2820501 V1.04 04/22/02
07.05.2002        08:44

Analyzer Mode  : Batch
Research Mode  : Off

Test PT 07.05.2002 10:30
No  Sample-ID Result Cuv.
1:  123       online 01a
    PT time1  15.4   sec
    PT INR    1.74
    PT conc   43.5   %
----------------------------------------
Finished 07.05.2002 10:45
State: Normal Termination
```

6.1.11 Interrupt a current run (User interrupt)

Follow the instructions in this section to interrupt a current run. The system is measuring as described in section 6.1.10 Start measuring, load cuvette bars.

The following display appears:

```
X PT Samples
03 123  --.--
```

• Press ESC to interrupt the run.

There may be a slight delay, before interruption of the current run is confirmed on the display.

The following display appears:

```
User interrupt (ESC)
Yes   no   stop   stat
 F1    F2    F3    F4
```

Select the method of interruption by using the function keys **F1-F4**:

Function key	Instruction	Meaning
F1	Yes	The run will only be interrupted after all cuvette bars in the measuring block have been completed, and results are available. The cuvette bars remaining in the sample rotor will be used later.
F2 or	No	The run will not be interrupted.
F3	Stop	The current run is interrupted immediately. The cuvette bars in the incubation and measuring position will not be used. The joblist will remain active.
F4	Stat	Places the instrument in STAT management mode, see section 6.3 STAT Management. Cuvette bars in the measuring block will be first completed.

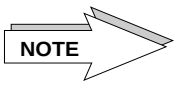
- Press **F4** to get into the STAT measurement and follow the instructions as indicated in section 6.3 STAT Management.

```
STAT Measurement
Edit Ins Prnt Start
```

- Press **ENTER** to run the selected tests.

6.1.12 Print results, send results to HOST

This section describes how to print results or send to a HOST computer. The system has an internal thermal printer to print all results, test and setup parameters, and error messages. Moreover, results can be sent to a connected HOST computer.



Use the RS 232C interface port to connect the HOST computer to the analyzer. The port is on the right side of the system below the socket for the optional barcode scanner. The port is marked RS 232. For further instructions, see section 5.1.4.4.

- Use the arrow keys (</>) to select <6 Result managem.> in the ROUTINE MENU.

```
ROUTINE MENU
< 6 Result managem. >
```

- Press **ENTER** to confirm.

The following display appears:

```
Result managem.
send list PRINT
 F1    F2   F3
```

Use **F1 = send** to send results to a HOST. To list the results in the display press **F2 = list.** Use the arrow keys (</>) to select between the patients. Use **F3 = print** to print the results on the internal printer.

By pressing **F1 = send** the following message will appear on the display for a short moment. The results and patient ID´s will be sent to the HOST computer.

```
sending results
```

By pressing **F2 = list** the results of each patient and test will be displayed accordingly. Using the arrow keys (</>) will display different patient results per test. Using the arrow keys up/down will display different test results per patient.

```
123           PT
1  result
```

After pressing **F3 = print** the following message will appear on the display for a short moment. The results will be printed on the internal printer.

```
printing results
```

The following display appears:

```
ROUTINE MENU
< 6 Result managem. >
```

After sending or printing the ROUTINE MENU will appear again. Press **ESC** to get back to the MAIN MENU.

6.1.13 Refill liquids, clean containers

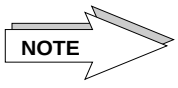
It is absolutely necessary to check the level in the distilled water container (green label) constantly and at the same time clean the waste water container regularly. If possible, the distilled water container should have a minimum of 1 litre. Always take care that no bubbles will be in the container. The bubbles might get into the tubing system which would influence level detection. **Use Distilled Water (aqua dest.) only!**

The containers should be checked every time before the system is switched on, before the measurement run at the latest.

The waste water container should be cleaned in a regular cycle. See section 8.1 Maintenance and Hygiene for further instructions.

The distilled water sensor (marked green) must be placed into the distilled water container (green label) before using the system. This sensor monitors the liquid level in the container and gives an error message if the level is too low. The following error message will be displayed:

```
STATE
Out of system liquid
```



The current measurement will be interrupted if not enough liquid is in the container during a measurement as the steel tubing cannot be washed.

The following error message will be printed:

```
Finished 07.05.2002 15:45
Status: no system liquid
```

To refill and clean the distilled water container follow the instructions below:

- Ensure that the system is not in a washing cycle or in menu < 5 Start measure >.
- Remove the **Distilled Water Sensor** from the **Distilled Water Container**.
- Empty the **Distilled Water Container** completely.
- Clean the inside of the container using a 70% alcohol solution and rinse it with distilled water. Avoid any alcohol residues in the container.
- Refill the **Distilled Water Container** with demineralised or distilled water. Do not use tap water.
- Place the **Distilled Water Sensor** into the container and continue with routine measurements.
- Every time the **Distilled Water Container** is refilled the **Waste Water Container** must be emptied.

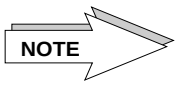
Always check the liquid levels to avoid unintended interruption of runs.

6.1.14 Empty and clean the waste water container

It is absolutely necessary to check the level in the waste water container (red label) constantly. The container should be checked every time before the system is switched on, before the measurement run at the latest.

The waste water sensor (marked red) must be placed into the waste water container (red label) before using the system. This sensor monitors the liquid level in the container and gives an error message if the level is too high. The following error message will be displayed:

```
STATE
Waste bottle full
```



The current measurement will be interrupted if the level is too high in order to avoid an overflow.

The following error message will be printed:

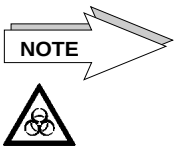
```
Finished 07.05.2002 15:45
Status: Waste bottle full
```

To empty and clean the waste water container follow the instructions below:

- Make sure that the instrument is not in a washing cycle or in menu < 5 Start measure >.
- Remove the **Waste Water Sensor** from the **Waste Water Container**.
- Empty the **Waste Water Container** completely. (See section Hazard and Precaution)

- Clean the inside of the **Waste Water Container** with 70% alcohol solution and rinse it with distilled water. Avoid any alcohol residues in the container.

- Return the **Waste Water Sensor** to the container and continue with measurements.



The waste water contains patient samples and test reagents and must be treated potentially infectious. Avoid any direct skin contact. Dispose of the waste water in compliance with biohazard and legal provisions.

6.2 Enter Test Parameter

Follow the instructions to change pre-defined test parameters. The descriptions will lead you through the TEST MENU and will help you to enter test parameters correctly.

6.2.1 Enter Reagent Specific Parameters

In this chapter learn how to enter reagent-specific parameters.

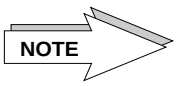
6.2.1.1 Enter a reference curve (PT, for example)

Follow the steps mentioned below to enter a reference curve. Here PT is used as an example since the reference curves for all methods will be entered in the same way. Therefore use the same steps to enter reference curves for the other methods, if necessary.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.



Before getting into the TEST MENU it is necessary to enter a number code (PIN). The system number code is preset to 11111 by the manufacturer. Change this code as described in section 6.4.6 Set PIN Code. Remember to note the code down and keep it at a safe place. It should be known to those users only who are authorised to operate the instrument.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default=11111).

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• To change or check test parameters press **ENTER** to confirm.

You can now select from the following display:

```
Select test:
PT   aPTT   FBG  END
```

• Select method **PT** by pressing **F1**. To enter the reference curve for **Fibrinogen** press **F3** accordingly. Press **F4 = END** to leave the menu without making any changes.

• Use the arrow keys (</>) until <4 1st Conversion> is displayed.

```
PT PARAMETER:
< 4 1st conversion >
```

• Press **ENTER** to confirm.

With the arrow keys (</>) choose between the following reference curve types:

```
PT 1st Conversion:     selection for:
< 1 None >             no conversion
< 2 Curve regr.>       regression
< 3 Curve interpol >   interpolation
```

• Use the arrow keys (</>) until < 3 curve interpol > is displayed.

• Press **ENTER** to confirm.

The following display appears:

```
     Time     Val[%]
1    11.5     100.0
```

The displayed values can be overwritten directly. First enter the time. Press the right arrow key (>) to set the decimal point. Press **ENTER** to confirm.

Enter the % - value with the number keys. Press **ENTER** to confirm. Use the left arrow key (<) to delete or overwrite.

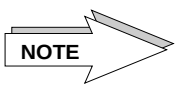
The system checks the reference curve points automatically whether they are plausible, i.e. falling concentration/activity must have rising time values and reverse. If the points are not plausible the system will beep.

The following display appears:

```
     Time     Val[%]
2    14.5      50.0
```

Enter the 2.reference curve point. Follow the instructions above. A minimum of 2 points must be defined; a maximum of 9 points can be entered.

• Press **ENTER** to confirm the entry.



To enter any additional point after having entered the second or any further point enter 0.0 s for the last time value. The remaining points will not be displayed. To enter more points next time enter the actual time value instead of 0.0 s and the remaining points will be displayed.

The following display appears:

```
PT PARAMETER:
< 4 1st conversion >
```

• Press **ESC** to leave this menu point.

Select <1 none> in <1st Conversion> menu to enter no reference curve.

• Press **ENTER** to confirm <1 none> and to deactivate the reference curve.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Press **ESC** again to get back into the MAIN MENU.

6.2.1.2 Enter ISI value

Follow the instructions to enter the ISI value.

• Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

• Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

• Enter the **PIN** code with the number keys (default= 11111).

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

• Press **F1** to select method PT.

Press **F4 = END** to leave the menu without making any changes.

The following display appears:

• Use the arrow keys (</>) until <5 2nd Conversion> is displayed.

```
PT PARAMETER:
< 5 2nd conversion >
```

• Press **ENTER** to confirm.

• Use the arrow keys (</>) until < 3 INR > is displayed.

The following display appears:

```
PT 2nd conversion
< 3      INR       >
```

• Then press **ENTER** to confirm.

The following display appears:

```
INR:
100% = 11.5 s
```

• Enter the 100% reference value (in sec.). The 100% Value can be taken from the tested calibration curve or from the used INR. INR is defined through standard plasma with a given mean value of 6 determinations definitions classification and the average value to be given in seconds.

The displayed value can be overwritten with the number keys. A maximum of 3 digits before the decimal point can be entered. Press the right arrow key (>) to set the decimal point.

Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

The following display appears:

```
INR:
ISI:  1.100
```

Enter the ISI-value according to the package insert of the reagent manufacturer. The displayed value can be overwritten with the number keys. A maximum of 3 digits after the decimal point can be entered. Press the right arrow key (>) to set the decimal point. Use the left arrow key (<) to delete or overwrite any entry. After the ISI-value has been entered the system will calculate the INR for each sample automatically.

• Press **ENTER** to confirm the entry.

The following display appears:

```
PT PARAMETER:
< 5 2nd conversion >
```

• Press **ESC** to leave this menu point.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Press **ESC** again to get back into the MAIN MENU.

6.2.1.3 Enter RATIO (APTT for example)

Follow the instructions to enter RATIO. Here aPTT is used as an example however Ratio for all methods will be entered in the same way. Therefore use the same steps to enter Ratio for the other methods, if necessary.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

- Press **F2** to select method aPTT.

If you want to enter Ratio for one of the other methods press either **F1** for **PT**. Press **F4 = END** to leave the menu without making any changes.

- Use the arrow keys (</>) until <5 2nd Conversion> is displayed.

The following display appears:

```
aPTT PARAMETER:
< 5 2nd conversion >
```

- Press **ENTER** to confirm.

- Use the arrow keys (</>) until <2 RATIO> is displayed.

The following display appears:

```
aPTT 2nd conversion
< 2      RATIO      >
```

- Press **ENTER** to confirm.

The following display appears:

```
Ratio:
100% =  20.0s
```

• Enter **Ratio** in seconds.

The displayed value can be overwritten directly. Press the right arrow key (>) to set the decimal point. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

The following display appears:

```
aPTT PARAMETER:
< 5 2nd conversion >
```

• Press **ESC** to leave this menu point.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Press **ESC** again to get back into the MAIN MENU.

6.2.1.4 Enter normal ranges (for example PT)

Follow the instructions to enter the normal ranges. Here PT is used as an example since the normal ranges for all methods will be entered in the same way. Therefore use the same steps to enter the normal ranges for the other methods, if necessary.

• Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

• Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

• Enter the **PIN** code with the number keys (default= 11111).

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

• Press **F1** to select method PT.

To set the normal ranges for one of the other methods press **F2** for **aPTT** or **F3** for **Fibrinogen**. Press **F4 = END** to leave the menu without making any changes.

• Use the arrow keys (</>) until <3 Normal ranges> is displayed.

The following display appears:

```
PT PARAMETER:
< 3 Normal range >
```

• Then press **ENTER** to confirm.

The following display to the maximum %-value appears:

```
PT Normal range:
max: 130.0 %
```

• Use the number keys to enter the %-value.

Press the right arrow key (>) to set the decimal point. A maximum of 4 digits before the decimal point can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

The following display to enter the minimum %-value appears:

```
PT Normal range:
min: 70.0 %
```

• Use the number keys to enter the %-value

A maximum of 2 digits before the decimal point can be entered. Press the right arrow key (>) to set the decimal point. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

The following display appears:

```
PT PARAMETER:
< 3 Normal range >
```

• Press **ESC** to leave this menu point.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Press **ESC** again to get back into the MAIN MENU.

6.2.2 Enter Method Parameter

This section describes how to enter the method parameters.

6.2.2.1 Enter single or double determinations

Follow the instructions to enter single or double determinations. In the following find two examples since the single and double determinations for all methods will be entered in the same way. Therefore use the same procedure accordingly.

Example 1

Set PT from double to single determination

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

- Press **F1** to select method **PT**.

To set another method press **F2** for **aPTT** or **F3** for **Fibrinogen**. Use **F4 = END** to leave the menu without making any changes.

- Use the arrow keys (</>) until <1 Replication> is displayed.

The following display appears:

```
PT PARAMETER:
< 1 Replication >
```

- Then press **ENTER** to confirm.

The following display appears:

```
PT Replication:
sngl  DBLE
F1    F2
```

DBLE = double

- Press **F1** to select **single (sngl)** determination. The determination selected will be displayed in capital letters.

The following display appears:

```
PT PARAMETER:
< 1 Replication >
```

- Press **ENTER** again to get to <1 Replication >.

Here, you can check whether single determination was accepted. **SNGL** will be displayed in capital letters.

- Press **ESC** to leave this menu point.

Example 2

Set APTT with 10% variation coefficient from single to double determination

<1 Modify test> in the TEST MENU has been selected.

```
TEST MENU:
< 1 Modify test >
```

- Press **ENTER** to confirm the selection.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

- Press **F2** to select method **aPTT**.

To set another method, press either **F1** for **PT** or **F3** for **Fibrinogen**. Use **F4 = END** to leave the menu without making any changes

- Use the arrow keys (</>) until <1 Replication> is displayed.

The following display appears:

```
aPTT PARAMETER:
< 1 Replication >
```

- Press **ENTER** to confirm.

The following display appears:

```
aPTT Replication:
SNGL  dble
```

SNGL = single

- Press **F2 = dbl** to select double determination. The determination selected will be displayed in capital letters.

The following display appears:

```
aPTT   max. CV:
        10%
```

Use the number keys to enter the variation coefficient. A maximum of 2 digits can be entered. With the left arrow key (<) you can delete or overwrite your entry.

- Press **ENTER** to confirm.

The following display appears:

```
aPTT PARAMETER:
< 1 Replication >
```

- Press **ESC** to leave this menu point.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press **ESC** to get back into the MAIN MENU.

6.2.2.2 Enter PT Test Parameter

In the following we have described how to enter reagent-specific data for **PT**.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

Enter the sample volume

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

• Press **F1** to select method **PT**.

Use **F4 = END** to leave the menu without making any changes.

• Use the arrow keys (</>) until <2 Measurement> is displayed.

```
PT PARAMETER:
< 2 Measurement >
```

• Press **ENTER** to confirm.

• Use the arrow keys (</>) until <1 Sample volume> is displayed.

The following display appears:

```
PT Measurement:
< 1 Sample volume >
```

• Press **ENTER** to confirm.

The following display appears:

```
PT Sample volume:
       50 µl
```

• Use the number keys to change the sample volume.

Remember that the total test volume must be between 125µl and 250µl. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter incubation time

• Use the arrow keys (</>) until <7 Incub. time> is displayed.

The following display appears:

```
PT Measurement:
< 7 Incub. Time >
```

• Press **ENTER** to confirm.

The following display appears:

```
PT Incubation:
        70s
```

• Use the number keys to change the incubation time. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter start reagent volume and the reagent lot number

- Use the arrow keys (</>) until <8 Start reagent> is displayed.

The following display appears:

```
PT Measurement:
< 8 Start reagent >
```

- Press **ENTER** to confirm.

The following display appears:

```
PT volume:
        100 µl
```

- Use the number keys to change the volume of the start reagent.

Remember that the total test volume must be between 125µl and 250µl. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

- Press **ENTER** to confirm the entry.

Enter the reagent lot number

The following display appears:

```
PT Lot No.:
        8888
```

- Use the number keys to enter or change the lot number of each method. Take the lot number from the package insert. A maximum of 9 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

- Press **ENTER** to confirm the entry.

Select reagent vial types

The system has an integrated reagent stir position to avoid sedimentation of the coagulation reagents. The reagents will be stirred immediately before pipetting and automatically within a defined time frame. In order to inform the system of the reagents to be stirred it is necessary to preset the reagent vial type and the stir function.

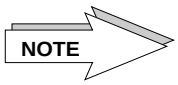
The manufacturer offers two reagent vial types. **You should use those reagent vials only** since the functionality of the system might be influenced otherwise. **A Teflon Stir Bar (supplied with the accessories) must be placed into the reagent vials**. Also the adapter rings (supplied with the accessories) must be used.
The following display to select a reagent vial type appears:

```
PT Bottle type:
< 6 4ml bottle >
```

- Use the arrow keys (</>) to determine which reagent vial type shall be used and whether the reagent shall be stirred.

Which varieties can be selected shows the following list.

Displayed	Meaning	Adapter ring	Teflon stir bar
<3 10ml bottle>	10 ml reagent vial without stir bar	white	no
<4 10ml bottle-R>	10 ml reagent vial with stir bar	white	yes
<6 4ml bottle>	4 ml reagent vial without stir bar	blue	no
<7 4ml bottle-R>	4 ml reagent vial with stir bar	blue	yes



Before positioning a reagent vial into the sample or reagent rotor make sure that it has been predefined for the method. The reagent vial types supplied by the manufacturer have different filling heights depending on their sizes (10 ml or 4ml). If you use the wrong vial type the level might not be detected correctly or the needle will touch the bottom of the wrong vial.

Enter maximum measuring time

If the vial type was selected the following display appears:

```
PT Measurement:
< 9 max meas time >
```

- Press **ENTER** to define the maximum measuring time.

The following display appears:

```
PT max. M-time:
        80s
```

- Use the number keys to enter or change the maximum measuring time. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

- Press **ENTER** to confirm the entry.

The following display appears:

```
PT Measurement:
< 1 Sample volume >
```

- Press **ESC** to leave this menu point.

The following display appears:

```
PT PARAMETER:
< 2 Measurement >
```

- Press **ESC** to leave this menu point.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

Press **ESC** to leave the menu without any further changes of method-specific data for other methods.

To change more press **ENTER** and follow the instructions as per section 6.2.2.3

6.2.2.3 Enter APTT Test Parameter

The following describes how to enter method-specific data for **aPTT**.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

Enter the sample volume

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

- Press **F2** to select method **aPTT**.

Press **F4 = END** to leave the menu without making any changes.

- Use the arrow keys (</>) until <2 Measurement> is displayed.

```
aPTT PARAMETER:
< 2 Measurement >
```

- Press **ENTER** to confirm.

- Use the arrow keys (</>) until <1 Sample volume> is displayed.

The following display appears:

```
aPTT Measurement:
< 1 Sample volume >
```

- Press **ENTER** to confirm.

The following display appears:

```
aPTT Sample volume:
       50 µl
```

• Use the number keys to enter or change the sample volume.

Remember that the total test volume must be between 125µl and 250µl. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter 1. Reagent Volume

• Use the arrow keys (</>) until <3 Reagent 1> is displayed.

The following display appears:

```
aPTT Measurement:
< 3 Reagent 1 >
```

• Press **ENTER** to confirm.

The following display appears:

```
aPTT volume:
         50 µl
```

• Use the number keys to change the reagent volume for APTT reagent.

Remember that the total test volume must be between 125µl and 250µl. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter a Lot Number

The following display appears:

```
aPTT Lot No.:
    123456789
```

• Use the number keys to enter or change the lot number.

You will find the number on the reagent package insert. A maximum of 9 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Select reagent vial types

The system has an integrated reagent stir position to avoid sedimentation of the coagulation reagents. The reagents will be stirred immediately before pipetting and automatically within a defined time frame. In order to inform the system of the reagents to be stirred it is necessary to predefine the reagent vial type and the stir function.

The manufacturer offers two reagent vial types. **You should use those reagent vials only** since the functionality of the system might be influenced otherwise. **A Teflon Stir Bar (supplied with the accessories) must be placed into the reagent vials**. Also the adapter rings (supplied with the accessories) must be used.

The following display appears:

```
aPTT Bottle type:
< 6  4ml Bottle >
```

- Use the arrow keys (</>) to determine which reagent vial type shall be used and whether the reagent shall be stirred.

Which varieties can be selected shows the following list.

Displayed	Meaning	Adapter ring	Teflon stir bar
<3 10ml bottle>	10 ml reagent vial without stir bar	white	no
<4 10ml bottle-R>	10 ml reagent vial with stir bar	white	yes
<6 4ml bottle>	4 ml reagent vial without stir bar	blue	no
<7 4ml bottle-R>	4 ml reagent vial with stir bar	blue	yes

NOTE

Before positioning a reagent vial into the sample or reagent rotor make sure that it has been predefined for the method. The reagent vial types supplied by the manufacturer have different filling heights depending on their sizes (10 ml or 4ml). If you use the wrong vial type the level might not be detected correctly or the needle will touch the bottom of the wrong vial.

Enter incubation time

- Use the arrow keys (</>) until <7 Incub. time> is displayed.

The following display appears:

```
aPTT Measurement:
< 7 Incub. time >
```

- Press **ENTER** to confirm.

The following display appears:

```
aPTT Incubation:
        120 s
```

- Use the number keys to enter or change the incubation time.

A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

- Press **ENTER** to confirm the entry.

Enter Start Reagent Volume

- Use the arrow keys (</>) until <8 Start reagent> is displayed.

The following display appears:

```
aPTT Measurement:
< 8 Start reagent >
```

- Press **ENTER** to confirm.

The following display appears:

```
CaCl2 volume:
       50 µl
```

- Use the number keys to enter or change the reagent volume for Calcium Chloride.

Remember that the total test volume must be between 125µl and 250µl. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

- Press **ENTER** to confirm the entry.

Enter a Lot Number

The following display appears:

```
CaCl2 Lot No.:
      123456789
```

- Use the number keys to enter or change the lot number.

The number is on the reagent package insert. A maximum of 9 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

- Press **ENTER** to confirm the entry.

Select Reagent Vial Types

Select the reagent vial type for calcium chloride and decide whether the reagent shall be stirred. To change the setting for the reagent vial type follow the instructions above.

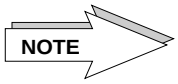
The following display appears:

```
CaCl2 Bottle type:
< 6 4ml Bottle >
```

- Use the arrow keys (</>) to determine which reagent vial type shall be used and whether the reagent shall be stirred.

Which varieties can be selected shows the following list.

Displayed	Meaning	Adapter ring	Teflon stir bar
<3 10ml bottle>	10 ml reagent vial without stir bar	white	no
<4 10ml bottle-R>	10 ml reagent vial with stir bar	white	yes
<6 4ml bottle>	4 ml reagent vial without stir bar	blue	no
<7 4ml bottle-R>	4 ml reagent vial with stir bar	blue	yes



Before positioning a reagent vial into the sample or reagent rotor make sure that it has been predefined for the method. The reagent vial types supplied by the manufacturer have different filling heights depending on their sizes (10 ml or 4ml). If you use the wrong vial type the level might not be detected correctly or the needle will touch the bottom of the wrong vial.

Enter Maximum Measuring Time

The following display appears:

```
aPTT Measurement:
< 9 max meas time >
```

• Press **ENTER** to confirm the maximum measuring time.

The following display appears:

```
aPTT max M-time:
       120 s
```

• Use the number keys to enter or change the maximum measuring time.

A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

The following display appears:

```
aPTT Measurement:
< 1 Sample volume >
```

• Press **ESC** to leave this menu point.

The following display appears:

```
aPTT PARAMETER:
< 2 Measurement >
```

• Press **ESC** to leave this menu point.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

Press **ESC** if no further change of method-specific data for other methods is requested.
To change more parameters press **ENTER** and follow the instructions as per section 6.2.2.4

6.2.2.4 Enter Fibrinogen Test Parameter

Follow the instructions to enter test-specific parameters.

• Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

• Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

• Enter the **PIN** code with the number keys (default= 11111).

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

• Select method **FBG** by pressing the function key **F3**. Press **F4 = End** to leave this menu without making any changes.

• Use the arrow keys (</>) until <2 Measurement> is displayed.

The following display appears:

```
FBG PARAMETER:
< 2 Measurement >
```

• Press **ENTER** to confirm.

Enter the Sample Volume

• Use the arrow keys (</>) until <1 Sample volume> is displayed.

The following display appears:

```
FBG Measurement:
< 1 Sample volume >
```

• Press **ENTER** to confirm.

The following display appears:

```
FBG Sample volume:
       100 µl
```

• Use the number keys to enter or change the sample volume.

Remember that the total test volume must be between 125µl and 250µl. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter 1. Reagent Volume (Dilution)

• Use the arrow keys (</>) until <2 Diluent> is displayed.

The following display appears:

```
FBG Measurement:
< 2  Diluent  >
```

• Press **ENTER** to confirm.

The following display appears:

```
FBG Diluent 1 + n:
         9.0
```

• Use the number keys to change the reagent volume (1+n) for the Dilution (Buffer).

A maximum of 3 digits can be entered. Press the right arrow key (>) to set the decimal point. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter a Lot Number (Buffer)

The following display appears:

```
FBG Diluent Lot No.:
      123456789
```

• Use the number keys to enter or change the lot number.

The number is on the reagent package insert. A maximum of 9 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter Incubation Time

• Use the arrow keys (</>) until <7 Incub. time> is displayed.

The following display appears:

```
FBG Measurement:
< 7  Incub. time  >
```

• Press **ENTER** to confirm.

The following display appears:

```
FBG Incubation:
       90 s
```

• Use the number keys to enter or change the incubation time.

A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter Start Reagent Volume

• Use the arrow keys (</>) until <8 Start reagent> is displayed.

The following display appears:

```
FBG Measurement:
< 8 Start reagent >
```

• Press **ENTER** to confirm.

The following display appears:

```
FBG volume:
       50 µl
```

• Use the number keys to enter or change the reagent volume for Fibrinogen.

Remember that the total test volume must be between 125µl and 250µl. A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Enter a Lot Number

The following display appears:

```
FBG Lot No.:
      123456789
```

• Use the number keys to enter or change the lot number of the method.

You will find the number on the reagent package insert. A maximum of 9 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

Select Reagent Vial Types

Select the reagent vial type for Fibrinogen and decide whether the reagent shall be stirred. To change the setting for the reagent vial type follow the instructions above.

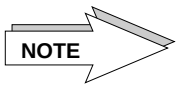
The following display appears:

```
FBG Bottle type:
< 7 4ml Bottle-R >
```

• Use the arrow keys (</>) to determine which reagent vial type shall be used and whether the reagent shall be stirred.

Which varieties can be selected shows the following list.

Displayed	Meaning	Adapter ring	Teflon stir bar
<3 10ml bottle>	10 ml reagent vial without stir bar	white	no
<4 10ml bottle-R>	10 ml reagent vial with stir bar	white	yes
<6 4ml bottle>	4 ml reagent vial without stir bar	blue	no
<7 4ml bottle-R>	4 ml reagent vial with stir bar	blue	yes



Before positioning a reagent vial into the sample or reagent rotor make sure that it has been predefined for the method. The reagent vial types supplied by the manufacturer have different filling heights depending on their sizes (10 ml or 4ml). If you use the wrong vial type the level might not be detected correctly or the needle will touch the bottom of the wrong vial.

Enter Maximum Measuring Time

• Use the arrow keys (</>) until <9 max meas time> is displayed.

The following display appears:

```
FBG Measurement:
< 9 max meas time >
```

• Press **ENTER** to confirm the maximum measuring time.

The following display appears:

```
FBG max M-time:
       100 s
```

• Use the number keys to enter or change the maximum measuring time.

A maximum of 3 digits can be entered. Use the left arrow key (<) to delete or overwrite any entry.

• Press **ENTER** to confirm the entry.

The following display appears:

```
FBG Measurement:
< 1 Sample volume >
```

• Press **ESC** to leave this menu point.

The following display appears:

```
FBG PARAMETER:
< 2 Measurement >
```

• Press **ESC** to leave this menu point.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

• Repeat pressing **ESC** until you are back in the MAIN MENU.

6.2.2.5 Print of Test Parameters (Fibrinogen for example)

The following describes how to print all reagent and method specific data (Print test) of a method. Here **Fibrinogen** is used for example however the other methods PT and APTT will be printed in the same way. Therefore follow the same steps to print the other methods. To print all methods together follow the instructions in section 6.2.5 Print of Test Parameters (Print test).

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press **ENTER** to confirm <1 Modify test> in the TEST MENU.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

- Select method **FBG** by pressing the function key **F3**.

If you want to print another method press either **F1** for **PT** or **F2** for **APTT**. If you press **F4 = End** you can leave this menu without changing anything.

- Use the arrow keys (</>) until < 6 Print test > is displayed.

```
FBG PARAMETER:
< 6 Print test >
```

- Press **ENTER** to confirm.

'Print test' will be displayed for a short moment.

```
Print test
```

The following display appears:

```
FBG PARAMETER:
< 6 Print test >
```

The reagent and method specific data will be printed automatically on the internal printer.

- Press **ESC** to leave this menu after printing is completed.

The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press **ESC** again in order to get back into the MAIN MENU.

Example of a test parameters print

```
 C2820501  V1.04   04/22/02
 07.05.2002          11:50

T3 = FBG Fibrinogen
--------------------------

 Replication     :  Double
 max. CV         :  10
 Sample volume   :  100µl
 Diluent         :  Bufer
   999992        :  1 + 9.0
 Incub. time     :  90 s
 Start reagent   :  FBG
   8888          :  50 µl
   4ml Bottle-R
 Airgap volume   :  5 µl
 Waste volume    :  5 µl
 max meas time   :  120 s
 Normal range
   150 --        400 mg/dl
 1st Convers.    :  Interpol
   9.9  sec      518 mg/dl
   12.8 sec      422 mg/dl
   16.6 sec      299 mg/dl
Extrapolation range
25  --           1200 mg/dl
 2nd Convers.    :  None
```

6.2.3 Read ChipCARD to load a new test (Read test)

In the following you will find how to load method and reagent specific data with a ChipCARD. Besides loading these data manually (see sections 6.2.1 and 6.2.2) you can use a ChipCARD. These ChipCARDs have been programmed with the method and reagent specific data of each reagent.

Each system is preset by the manufacturer with the test settings for PT, APTT and FIBRINOGEN. These test settings can be changed or overwritten with a ChipCARD.

NOTE

3 tests can be loaded on the system at one time, e.g. PT, APTT, and Fibrinogen. If you want to load a new test with changed settings one test from the system will be overwritten, i.e. deleted.

CoaLAB 6000
Default ChipCard
PT
REF 30.000.1196
P-ID G 15 2 0220
To install, refer to operators manual prior to use.
Weitere Informationen zur Installation finden Sie im Benutzerhandbuch.
Reportez-vous au manuel d´utilisation pour l´installation.
Para la instalación, consultar antes el Manuel del usuario.
Per l´installazione, leggere Il manuale di instruzioni prima dell´utilizo.
+15 +30 °C
LABiTec GmbH
22926 Ahrensburg, Germany
LABiTec

The ChipCARDs contain all reagent and test specific data such as lot no., reference curve, incubation or activating time, expiry date of the reagent, ISI, etc. Once you have loaded a ChipCARD no further settings have to be made at the system. All data which had been entered manually beforehand will be overwritten with the data of the ChipCARD.

For further information regarding availability, prices and application of ChipCARDs contact your distributor or manufacturer.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

- Select <2 Read test> in the TEST MENU.

```
TEST MENU:
< 2 Read test >
```

- Lift the **printer cover** above the keyboard.
  The ChipCARD reader is below the printer module.

- Insert the ChipCARD with the **chip facing down** into the slot of the reading module. Leave the ChipCARD in the reader.

- Press **ENTER** to confirm.

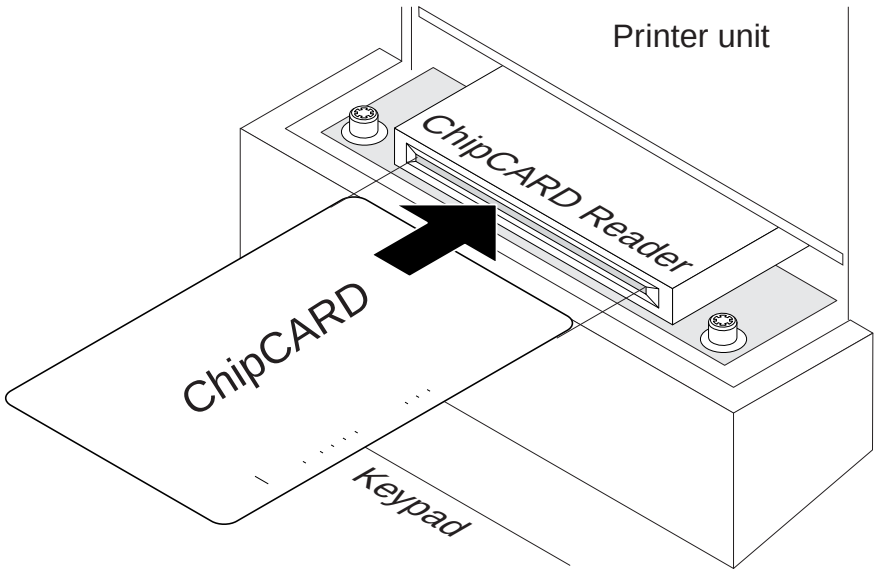


Figure 15 How to load a ChipCARD

The following display appears:

```
Overwrite test:
PT   aPTT   FBG   END
```

- Use the function keys **F1 - F3** to select the test to be overwritten by the ChipCARD. By pressing **F4 = End** you can leave this menu without making any change.

The following display appears:

```
Read test
```

'Read test' will be displayed for a short moment. The instrument reads the ChipCARD.

The following display appears:

```
Test loaded:
Name of loaded test
```

A message follows that the test of the system was overwritten by the ChipCARD test.

- Press **ENTER** to confirm.

If the ChipCARD was inserted wrong or not at all the following error message will appear:

```
E R R O R
No CARD found
```

- Press **ENTER** to confirm this message and repeat the procedure.

If you inserted a ChipCARD of which the test had been loaded already the following error message will be displayed:

```
      E R R O R
 Test already loaded
```

- Press **ENTER** to confirm this message and repeat the procedure with another ChipCARD.

Withdraw the ChipCARD from the reader and close the printer cover again. If you want to overwrite more tests of the system repeat the above steps for all new tests.

The following display appears:

```
TEST MENU:
< 2 Read test >
```

- Press **ESC** in order to get back into the MAIN MENU.

6.2.4 Save Tests on a ChipCARD

Find below how to write test parameters, including calibration curve, to a ChipCARD and how to save the data. Editable ChipCARDs can be bought from the manufacturer, see Chapter 8.5 Accessories and Consumables.

It is possible to save test parameters for a specific reagent lot so that you can use this test again when a reagent of the same lot is used. No parameters have to be entered manually.

Since the procedure of saving test parameters on a ChipCARD is the same for all tests we have taken the PT test as an example.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

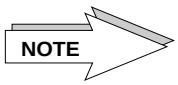
The following display appears:

```
TEST MENU:
< 1 Modify test >
```

- Press the arrow keys (</>) until <5 Write test> is displayed.

```
TEST MENU:
< 5 Write test >
```

- Press **ENTER** to select the function.
- Insert the ChipCARD into the reader. Use either a blank CARD or an already edited ChipCARD. If you select a used ChipCARD remember that all data on the ChipCARD will be overwritten.



Be careful not to use and overwrite the Default ChipCARD (also supplied in the accessories).

The following display appears:

```
Select test:
PT    aPTT    FBG   END
F1     F2     F3    F4
```

- Select the test to be saved by pressing one of the function keys **F1 - F3**. By pressing **F4 = End** you can leave this menu without making any changes.

The following display appears:

```
Write test
```

'Write test' will be displayed while the data is written to the ChipCARD.

```
Test written:
Name of written test
```

An acoustic signal will be heard at the end of saving.

- Press **ENTER** to confirm.
- Remove the edited ChipCARD and write all test relevant information on it for proper identification.
- Put the printer cover back into its position.
- Press **ESC** to get back into a higher menu level.

Error messages

If the ChipCARD has been inserted wrong or not at all the following message will appear:

```
      E R R O R
    No CARD found
```

- Press **ENTER** to confirm and repeat the procedure after the ChipCARD has been inserted.

If you used the Default CARD the following message will appear:

```
      E R R O R
 Write protected card
```

- Press **ENTER** to confirm and repeat the procedure with another ChipCARD.

If a defective ChipCARD was used the following message will appear:

```
E R R O R
No CARD found
```

- Press **ENTER** to confirm and repeat the procedure with a new ChipCARD.

6.2.5 Print of Test Parameters (Print test)

Follow the instructions to print all reagents and test specific data (print test) of a method. We have used Fibrinogen for example however the other methods PT and APTT will be printed in the same way. Therefore follow the same steps to print the other methods.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

- Use the arrow keys (</>) until <3 Print test> is displayed.

```
TEST MENU:
< 3 Print test >
```

- Press **ENTER** to confirm.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

- Select method **FBG** by pressing the function key **F3**. If you want to print another method press either **F1** for **PT** or **F2** for **APTT**. If you press **F4 = End** you can leave this menu without changing anything.

The following display appears:

```
Print test
```

The test specific data for Fibrinogen will be printed automatically on the internal printer.

- Press **ESC** to get back into the MAIN MENU.

6.2.6 Delete Test

In the following we have described how to delete tests which are stored in the system. Remember that all reagent and test specific data of this method will be deleted completely.

- Use the arrow keys (</>) to select <2 TEST MENU> in the MAIN MENU.

```
MAIN MENU:
< 2 TEST MENU >
```

- Press **ENTER** to confirm.

The following display appears:

```
TEST MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

- Use the arrow keys (</>) until <3 Print test> is displayed.

```
TEST MENU:
< 4 Erase test >
```

- Press **ENTER** to confirm.

The following display appears:

```
Select test:
PT   aPTT   FBG  END
```

- Using the function keys F1 - F4 select the test to be deleted. By pressing **F4 = End** you can leave this menu without making any changes.

The following display appears:

```
Really erase test?
YES   no
```

You will be asked again whether you really want to delete the selected test. Use either **F1 = YES** or **F2 = NO**.

```
TEST MENU:
< 4 Erase test >
```

- Confirm deletion by pressing **F1 = YES.**

- Press **ESC** to get back into the MAIN MENU.

6.3 STAT Management

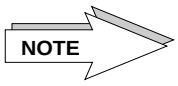
In the following we have described the STAT management which explains how to run emergency tests during routine operation.

Introduction

Up to 3 samples may be preset for STAT on the sample/reagent rotor, see section 6.4.2 Define STAT positions in the sample rotor. If you want to run STAT tests you can either:

1) Preset up to 3 samples on the rotor for STAT beforehand, see section 6.4.2. Positions 16 to 18 will be used on the rotor.

2) Or make no reservations of any special position on the rotor. The system will position STAT tests automatically into the next available rotor positions. If all sample rotor positions are occupied by routine measurements and no STAT positions have been reserved you have to clear the complete joblist first.



We recommend to pre-set 1-3 positions for emergency measurements to run STAT tests during routine operation.

Follow section 6.1.11 Interrupt a current run (User interrupt) run if you are in routine operation and want to run a STAT test. All routine tests which have not been worked off will remain in the joblist and will be measured after the STAT test.

Follow the instructions for STAT measurements:

- Use the arrow keys (</>) to select <3 STAT MANAGEMENT> in the MAIN MENU.

```
MAIN MENU:
< 3 STAT MANAGEMENT >
```

- Press **ENTER** to confirm.

The following display appears:

```
STAT MANAGEMENT:
Edit Ins  Prnt Start
```

If you are in routine operation you can go directly into this method by pressing **F4 = STAT** (see section 6.1.11 Interrupt a current run (User interrupt). Before entering the STAT joblist the running measurements from routine operation will be completed. Using the function keys **F1 - F4** select the desired action from the table:

Function key	Order	Meaning
F1	Edit	If there is a joblist from routine operation you can transfer patients from this list into the STAT job list. Further you can edit or change any existing STAT joblist.
F2	Ins	To enter new emergency patients into the STAT joblist. The routine joblist will not be influenced, if free positions are available.
F3	Prnt	To print the STAT joblist.
F4	Start	To begin STAT measurements.

Example **F1 = Edit**

- **Change from ROUTINE into STAT operation:**

- Press **F1** for editing.

The following display appears:

```
01 S-ID: 30001
pt   aptt   fbg   all
```

The first patient of your ROUTINE joblist will be displayed and can be transferred into the STAT joblist. With the function keys **F1-F4** you can select the methods. The selected test will be displayed in big letters. With the arrow keys up and down the next sample can be called for or skipped over.

The patient samples that have been transferred from ROUTINE into the STAT joblist will be deleted in the ROUTINE list. All patient samples which have not been transferred into the STAT list will remain in the ROUTINE list for later measurements.

- Press **ENTER** to confirm.

The following display appears:

```
STAT MANAGEMENT:
Edit Ins  Prnt Start
```

If you want to print the STAT joblist press **F3 = print**. If you want to start STAT measurements press **F4 = Start**. For further entry of new STAT patients press **F2 = Ins** and follow the example below.

Example **F2 = Insert**

Enter new patient samples into the STAT joblist:

- Press **F2** for inserting.

The following display appears:

```
05 S-ID: 30005
pt   aptt   fbg   all
```

The system will extend the next available sample rotor position automatically so that you can place the new primary tube. Press **F1-F4** to select the methods. If you want to change the patient ID press the left arrow key (<) until the displayed ID is deleted. Now you can enter another ID with the number keys.

- Press **ENTER** to confirm.

The following display appears:

```
06 S-ID: 30006
pt   aptt   fbg   all
```

If you want to insert further patient samples into the STAT joblist follow the steps as mentioned before. Press **ESC** to leave this menu.

The following display appears:

```
STAT MANAGEMENT:
Edit Ins  Prnt Start
```

Example **F3 = Prnt**

Print STAT joblist:

- Press **F3** for printing.

The following display appears:

```
Printing joblist
```

The STAT job list will be printed automatically on the internal printer.

After the print the following message will be displayed:

```
STAT MANAGEMENT:
Edit Ins  Prnt Start
```

Example of the printed STAT joblist:

```
C2820501 V1.04 04/22/02
07.05.2002        11:50

STAT Joblist
T1   =  PT    PT
T2   =  APTT  APTT
T3   =  FBG   Fibrinogen

No   Sample-ID  T1  T2 T3
1    30001      x   x  x
2    30002      x   x  x
3    30005      x   x  x
-------------------------
```

Example **F4 = Start**

Start the STAT joblist:

- Press **F4** for start.

The following display appears:

```
Prepare measure…
```

The following display appears:

```
INFO
Check waste box
```

'Check waste box' will be displayed for a short moment every time a job list has been entered. If used cuvette racks are still in the waste box we recommend to empty it.

The following display appears:

```
Insert cuvette bar
and close cover
```

The system calculates from the joblist automatically how many cuvette racks will be needed. The sample rotor extends the next position automatically to load a cuvette rack. This procedure will be repeated until all cuvette racks necessary for the measurements have been positioned in the sample rotor.

- Press **ENTER** to confirm.

The sample rotor will extend the next available reagent position automatically. Insert the adapter ring and the reagent vial for the selected method. Remember to use predefined reagent vial types only (see Chapter 6.2.2.2). If reagents are already loaded the analyzer will check reagent volume and starts measurement automatically.

Test will not function without any reagents.

The necessary reagent volume will be displayed.

```
1: washer:
LOAD 0.5ml      skip
```

If the reagent vial is in the sample rotor you can either select

F1 (load) or ENTER = the reagent has been loaded and confirmed.

F4 (skip) = the reagent has not been loaded no entry confirmed continue to next reagent.

- Press **F1** or **ENTER** in this case to confirm.

The following display appears:

```
2: Buffer    9999992
LOAD 0.4ml      skip
```

- The sample rotor position will be extended automatically. Load Buffer into the sample rotor and confirm with **F1**.

  If you want to skip over this position and not load Buffer press **F4**.

The following display appears:

```
3: FBG          8888
LOAD 0.3ml      skip
```

- The sample rotor position will be extended automatically. Load Fibrinogen into the sample rotor and confirm with **F1**.

  If you want to skip over this position and not load Fibrinogen press **F4**.

The following display appears:

```
4: CaCl2    12345678
LOAD 0.3ml      skip
```

- The sample rotor position will be extended automatically. Load Calcium Chloride into the sample rotor and confirm with **F1**.

  If you want to skip over this position and not load Calcium Chloride press **F4**.

The following display appears:

```
5: aPTT    999999995
LOAD 0.3ml      skip
```

- The sample rotor position will be extended automatically. Load aPTT reagent into the sample rotor and confirm with **F1**.

  If you want to skip over this position and not load aPTT reagent press **F4**.

The following display appears:

```
6: PT      123456789
LOAD 0.3ml      skip
```

- The sample rotor position will be extended automatically. Load PT reagent into the sample rotor and confirm with **F1**.

  If you want to skip over this position and not load PT reagent press **F4**.

The following display appears:

```
Prepare measure…

```

After having placed the last reagent into the sample rotor of the system will check the reagents automatically. Especially the volume will be checked. If reagents are missing or the volume is insufficient the following message will be displayed:

```
6: PT      123456789
Only x.x of x.x ml
```

You can load the missing reagent now.

- Press **ENTER** to confirm.

The following display appears:

```
Pipettor     M-Block
37.4          38.4
```

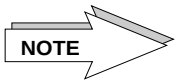
The message Pipettor / Tubing gives a short status on the temperature of the measuring block and the pipettor. If the temperature is not correct, i.e. 37°C or 38°C, this message will be displayed until the temperature has been reached.

The following display appears:

```
18 Samples
No Results available
```

The system starts measuring. The message displayed shows how many samples still have to be worked off. The results will be printed automatically on the internal printer.

If results are not available yet the message 'No results available' will be displayed.



You can interrupt the STAT measurement by pressing the ESC-key. Follow the instructions as per Chapter 6.1.11 Interrupt a current run (User interrupt).

After the measurement has been completed a beep will be heard and the following message will be displayed:

```
STATUS
Normal Termination
```

Example for a result print:

```
 C2820501 V1.04 04/22/02
 07.05.2002         11:50
 Analyzer Mode  : Batch
 Research Mode  : Off

**** STAT MANAGEMENT ****
Test PT  07.05.2002 15:10
 No Sample-ID  Result Cuv.
 1  30001      online 01ab
    PT time1   11.7   sec
    PT time2   11.7   sec
    PT mean    11.7   sec
    PT INR     1.03
    PT conc    93.75  %

Test aPTT 07.05.2002 15:17
 No Sample-ID  Result Cuv.
 1  30001      online 01ef
    aPTT time1 35.3   sec
    aPTT time2 35.7   sec
    aPTT mean  35.5   sec
    aPTT Ratio 1.77
--------------------------
  **END STAT MEAUREMENT**
Finished  07.05.2002 15:45
State: Normal Termination
```

6.4 General Setting (SETUP MENU)

Basic settings of the system

Before working with the system in routine operation several basic settings must be entered. The following default parameters have been preset by the manufacturer:

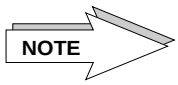
Standard settings of the system

System parameters

Name	Standard setting
Primary tube	Sample Cup
Reserved STAT positions	0
Analyzer mode	Batch
PIN code	11111
Language	English
Printer mode	list
Beeper Setup	long

Reagent or Method Parameters:

Name	Standard setting of reagent or method parameters			
	PT	**aPTT**	**Fibrinogen**	**Washing Solution**
Determination	double	double	double	-
Variation coefficient	5%	5%	10%	-
Sample volume	50 µl	50 µl	100 µl	-
Reagent 1 / Diluent	**-**	**APTT**	**Bufer**	**Washer**
Reagent volume	-	50 µl	1 + 9.0	-
Reagent vial type	-	4 ml	4 ml	10 ml
Reagent stir function	-	inactive	-	-
Adapter ring	-	blue	blue	White
Teflon stir bar	-	no	no	No
Incubation time	70 sec	180 sec	90 sec	-
Start reagent	**PT**	**$CaCl_2$**	**FBG**	**-**
Reagent volume	100 µl	50 µl	50 µl	-
Reagent vial type	4 ml	4 ml	4 ml	-
Reagent stir function	active	inactive	inactive	-
Adapter ring	Blue	blue	blue	-
Teflon stir bar	Yes	no	yes	-
Airgap volume	5 µl	5 µl	5 µl	-
Waste volume	5 µl	5 µl	5 µl	-
Max. meas. time	80 sec	120 sec	120 sec	-
Normal range	7.0-13.0 sec	25-45 sec	150-400 mg/dl	-
1. conversion	none	none	regression	-
	dep. on lot.	-	dep. on lot.	-
Extrapolation range	-	-	45-1000 mg/dl	-
2. conversion	none	none	none	-
100%	dep. on lot	-	-	-
ISI	dep. on lot	-	-	-

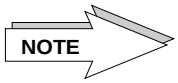


If you do not wish to change any of the manufacturer's preset default settings continue with ROUTINE operation, see section 6.1.

If you want to change any of these settings follow the steps below:

6.4.1 Define Primary Tubes

Before entering a joblist in routine operation the primary tubes can be selected. The system has a recommended number of different types. If you use the Sample cup which is preset by the manufacturer you can ignore the following instructions.

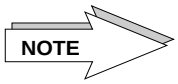


To secure perfect operation of the system only recommended primary tubes should be used.

- Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

- Press **ENTER** to confirm.



Before getting access to the SETUP MENU a PIN code has to be entered with the number keys. The preset code is 11111. You can change this code by following the instructions as per chapter 6.4.6 Set PIN Code. Remember to write this code down and keep it at a safe place, accessible to authorised users only.

The following display appears:

```
SETUP MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).
- Press the arrow keys (</>) until <1 Primary Tube> is displayed in the SETUP MENU.

The following display appears:

```
SETUP MENU:
< 1 Primary Tube >
```

- Press **ENTER** to confirm.

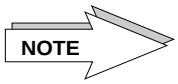
The following display appears:

```
Primary Tube:
< 1 Sample Cup >
```

The displayed primary tube is the type entered last. By pressing the arrow keys (</>) you can select another type.

• Press **ENTER** to confirm.

The following list will give an overview of the primary tubes which can be used on the system.



Never go below the recommended dead volume or results may be affected. Only one type can be used at a time. A mixture of tubes may damage the pipettor.

Pos No.	Primary Tube	Dead volume	Max. Volume	Manufacturer
1	1 Sample Cup	150 µl	4.000 µl	LABiTec
2	2 Vacutainer	-	4.500 µl	Beckton & Dickinson
3	3 Monovette	-	3.000 µl	Sarstedt

The following display appears:

```
SETUP MENU:
< 1 Primary Tube >
```

• Press **ESC** to get back into the MAIN MENU.

6.4.2 Define STAT positions in the sample rotor

Follow the instructions to define or reserve STAT positions in the sample rotor. A maximum of 3 positions may be reserved for STAT samples. If no STAT positions have been reserved, the instrument will use the next free position available.

• Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

• Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
PIN
```

• Enter the **PIN** code with the number keys (default= 11111).

• Press the arrow keys (</>) until <2 No of STAT pos.> is displayed in the SETUP MENU.

The following display appears:

```
SETUP MENU:
< 2 No of STAT pos >
```

• Press **ENTER** to confirm.

The following display appears:

```
No of STAT pos
No of STAT pos:  0
```

The displayed number of reserved STAT positions is the number entered last. By pressing the number keys (0-3) you can enter the selected number of STAT positions.

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
< 2 No of STAT pos >
```

- Press **ESC** to get back into the MAIN MENU.

6.4.3 Date and Time

As the date and time are printed at the top of each run's results, it is important that they are entered accurately.

- Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).
- Press the arrow keys (</>) until <3 Date / Time> is displayed in the SETUP MENU.

The following display appears:

```
SETUP MENU:
< 3 Date / Time >
```

- Press **ENTER** to confirm.

The following display appears:

```
Date / Time:
17.04.2002  16:34:58
```

- Use the number keys to enter the date and time. With the left arrow key (<) you can delete or overwrite.

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
< 3 Date / Time >
```

- Press **ESC** to get back into the MAIN MENU.

6.4.4 Printer Setup

This section describes the printer configurations. You can set the operation mode of the analyzer internal printer according to your requirements.

- Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

- Press the arrow keys (</>) until <4 Printer setup> is displayed in the SETUP MENU.

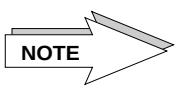
The following display appears:

```
SETUP MENU:
< 4 Printer setup >
```

- Press **ENTER** to confirm.

```
Printer setup:
AUTO  list   on  off
 F1    F2     F3  F4
```

Using the function keys **F1-F4,** select the desired operation mode from the table below. The activated operation mode will be displayed in bold letters.



Please note, by using the function key F4 = off in general no print out will be done by the internal printer.

Function key	Message displayed	Meaning
F1	auto	All printing orders will be transmitted to the internal printer. The measurement results will be printed test oriented (online), that means according to the availability of results.
F2	list	All printing orders will be transmitted to the internal printer. The measurement results will be printed patient oriented, that means once all results per patient are available.
F3	on	No online print of results. To print results, activate **'print results'** see section 6.1.12 Print results, send results to HOST. All other printing orders will be executed.
F4	OFF	Turns the internal printed off. No printing will occur.

The following display appears:

```
SETUP MENU:
< 4 Printer setup >
```

- Press **ESC** to get back into the MAIN MENU.

6.4.5 Beeper Setup

This section allows the user to set the length of the signals when a status massage or error has occurred or testing is complete. See below the 3 basic signal tones you can choose from.

1.) **Long**, followed by repeatedly short tones warns of future action necessary and can be switched off by acknowledging the action and confirming it with the ENTER key. Same tones will also sound by pressing a key on the keyboard to acoustically confirm the entry.

2.) **Short**, followed by a one-time signal tone, warns that the system waits for the next command to complete the action and remains in this position until the operator gives the next command and confirm it with the ENTER key. Same tones will also sound by pressing a key on the keyboard to acoustically confirm the entry.

3.) **Off**, no signal tones will be carried-out.

- Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).

• Press the arrow keys (</>) until < 5 Beeper Setup > is displayed in the SETUP MENU.

```
SETUP MENU:
< 5 Beeper setup >
```

• Press **ENTER** to confirm.

The following display appears:

```
Beeper setup:
long  short      off
F1    F2         F4
```

With the function keys **F1 + F2** you can select the beeper mode. **F4** will deactivate the beeper. The activated mode will be displayed in big letters.

The following display appears:

```
SETUP MENU:
< 5 Beeper setup >
```

• Press **ESC** to get back into the MAIN MENU.

6.4.6 Set PIN Code

In the following we have explained how to change the PIN code of the system. The PIN is preset to **11111** by the manufacturer and will be active until modified by the user. The PIN code will be asked for before entering the TEST MENU and the SETUP MENU.

• Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

• Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
PIN
```

• Enter the **PIN** code with the number keys (default= 11111).

• Press the arrow keys (</>) until <6 Modify PIN> is displayed in the SETUP MENU.

The following display appears:

```
SETUP MENU:
< 6 Modify PIN >
```

• Press **ENTER** to confirm.

The following display appears:

```
Modify PIN
New PIN: 11111
```

The actual PIN code will be displayed. You can change it with the number keys. A maximum of 5 numbers can be entered. The PIN code has to be defined between 1 until 65535. Use the left arrow key (<) if you want to delete or overwrite your entry.

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
< 6 Modify PIN >
```

- Press **ESC** to get back into the MAIN MENU.

6.4.7 Language

Follow the instructions if you want to change the language in the system. You can select between **English** and **German**.

- Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).
- Press the arrow keys (</>) until <7 Language> is displayed in the SETUP MENU.

The following display appears:

```
SETUP MENU:
< 7 Language >
```

- Press **ENTER** to confirm.

The following display appears:

```
Select language:
ENG   deu       end
F1    F2        F4
```

The activated language will be displayed in big letters. With the function keys **F1 = English** and **F2 = German** you can select the desired language. If you press **F4 = end** you will leave this menu without changing anything.

The following display appears:

```
SETUP MENU:
< 7 Language >
```

- Press **ESC** to get back into the MAIN MENU.

6.4.8 Print of Setup Parameters

Follow the instructions to print the parameters described in section 6.4 General Setting (SETUP MENU) on the internal printer. Printing the SETUP parameters provides an overview of the general setup of the system.

- Use the arrow keys (</>) to select <4 SETUP MENU> in the MAIN MENU.

```
MAIN MENU:
< 4 SETUP Menu >
```

- Press **ENTER** to confirm.

The following display appears:

```
SETUP MENU:
PIN
```

- Enter the **PIN** code with the number keys (default= 11111).
- Press the arrow keys (</>) until <8 Print Setup> is displayed in the SETUP MENU.

```
SETUP MENU:
< 8 Print Setup >
```

- Press **ENTER** to confirm.

The following display appears:

```
Print Setup
```

The SETUP parameters will be printed on the internal printer.

The following display appears:

```
SETUP MENU:
< 8 Print Setup >
```

- Press **ESC** to get back into the MAIN MENU.

6.5 Removing cuvette bars from the system

In the following chapter we have described how to remove cuvette bars from the measuring block.

• Use the arrow keys (</>) to select <5 UTILITY MENU> in the MAIN MENU.

```
MAIN MENU
< 5 UTILITY MENU >
```

• Press **ENTER** to confirm.

The following display appears:

```
UTILITY MENU:
< 1 Init Instrument >
```

• Press **ENTER** to confirm the message.

The following display appears:

```
Init Instrument
Init ...  (ESC=Stop)
```

The motors and the diluter will be initialised. During this phase the cuvette racks in the measuring block will be moved one position to the right and will be ejected from the measuring block.

The following display appears:

```
Init Instrument
Flush ...  (ESC=Stop)
```

Then the liquid system will be initialised. Liquids are pumped into the tubing's.

• Press **ESC** if you want to finish initialisation.

The following display appears:

```
UTILITY MENU:
< 1 Init Instrument >
```

• Press **ESC** to get back into the MAIN MENU.

6.6 Switch OFF the system

Prior to switching off the system make sure the system is cleaned and disinfected from all residues of reagent and sample material inside the liquid system as well as from the outer side of the analyzer. Depending on how long you would like to shut down the system it is necessary to follow different wash/flush cycles to avoid any residues of reagents/samples will remain in the liquid system.

To clean/disinfect the system follow the instructions as described in sections 6.1.2 Rinsing with distilled water, 6.1.3 Disinfection of waste tubing (Terralin), change of FW-Filter or 6.1.4 Rinsing with Washing Solution.

In case of a long term shut down it is recommended to also dry the system completely. Follow the instructions in section 8.8 Packing of the system, preparation of transport as described under 3. - 6. This procedure should be done if the shut down time exceeds 4 weeks.

Remove all reagents must be removed from the sample/reagent rotor. Follow the instructions in section 6.1.5 Loading and unloading reagents.

Remove all samples/cups from the sample/reagent rotor positions 1-18 by erasing the joblist. Follow the instructions described in section 6.1.6 Delete joblist, delete samples. Make sure all results of the current joblist are printed out prior to erasing the joblist. Once the joblist has been deleted no results will be available anymore.

Make sure that finally the instrument is free of cuvette bars, vials, cups and adapter rings.

Now the system can be switched OFF by setting the power switch to the position **O = ON**.

7 Failures

Possible error messages, their causes and trouble shooting are described in this section. These failures or status messages can be displayed as well as printed. The messages will be differentiated according to the following scheme:

Status messages:

System messages for the general information of the user. These are no errors/failures.

Application errors:

Failures/errors to be corrected by the user.

Non-fatal errors:

Functional system errors to be corrected by the user.

Fatal errors:

Errors to be corrected by the technical customer service only. Contact your authorised distributor or the manufacturer.

7.1 Status Messages

Message	Cause	Corrections

Module:<name> (<Adr>)
Timeout Req = <ID>
 	
Example
`Module: Control (07)`
`Timeout Req = 43`
	Message has no influence on functions of the system.
	No influence on measurements.
		Message only displayed and printed out.

STATE Out of system liquid	The dist. water container is empty	Fill water into the container see chapter 6.1.13.
STATE Waste bottle full	The waste water container is full.	Empty the container see chapter 6.1.14.
STATE System liquid error	The dist. water container is empty and/or the waste water container is full.	Fill dist. water container and/or empty waste water container.
STATE Missing reagent	A reagent was not loaded or positioned in the rotor	Reload or position missing reagent, see chapter 6.1.5.
STATE User Interrupt	Measurement interrupted by the user.	See Chapter 6.1.11.
STATE Normal Termination	A routine run was completed.	Message for the user.
INFO No Space for new Sample	More than 18 possible samples were to be loaded or no further positions available due to STAT positions reserved.	Further samples must be measured later. Reserved STAT positions could be reduced, see chapter 6.4.2.
INFO No samples loaded	No joblist available, i.e. no samples have been loaded.	Work out joblist and load samples, see chapter 6.1.7
ERROR Test volume too big	The permissible volume was exceeded.	Check volume settings for sample and reagent volume. (Test volume 125 µl-250 µl)
ERROR Test volume too low	The volume is too low.	Check volume settings for sample and reagent volume. (Test volume 125 µl-250 µl).
No print out	Printer is not active	Switch on printer, refer to chapter 6.4.4Printer Setup

7.2 Application Errors

Message	Cause	Corrections
Module: Control (07) Move Error Motor 0	Cuvette rack or sample cup was not positioned properly.	Check correct position of racks and/or sample cups. Does this error appear again, see fatal errors!
Module: Control (07) Move Error Motor 3	Cuvette rack in the rotor or in the measuring block is not positioned properly.	Either remove rack with Init Instrument (Chapter 6.5) or switch Instrument off and remove cuvette rack manually. Does this error appear again, see fatal errors!
Module: Diluter (03) Move Error Motor 0	The syringe is not mounted properly to the diluter or the space below the syringe is too small.	Check correct mounting of syringes (Chapter 5.1.4.1) or clear space below
ERROR No chip card found	A ChipCARD was not inserted properly or not at all.	Re-insert ChipCARD, repeat procedure (Chapter 6.2.3).
ERROR Test already loaded	The selected test on the Chip-CARD had already been loaded.	No corrections necessary.
ERROR Too many reagents	The number of reagent positions does not correspond to the number of loaded methods.	A method must be deleted (Chapter 6.2.6).
ERROR Not enough sample	Not enough samples for pipetting or a wrong primary tube used.	Refill sample or replace primary tube (Chapter 6.4.1).
ERROR Not enough reagent	Not enough reagents available or a wrong reagent vial used.	Refill reagent or replace reagent vial.
ERROR Incubation warning	The incubation time was exceeded.	Check method parameters regarding incubation times, maximum measuring times and activation times (reagent 3).
ERROR pipettor not conn.	Flat cable to pipettor is not connected properly or cable has been damaged.	Check correct connection of cable. Has cable been damaged contact customer service.
fresh water sensor No sensor 1 found	Fresh Water Sensor is not connected.	Switch Instrument off. Connect fresh water sensor. Re-start system.
Waste water sensor No sensor 2 found	Waste Water Sensor is not connected.	Switch Instrument off. Connect waste water sensor. Re-start system.
ERROR Level Sensor Error	Liquid between Level Sensor and needle at the pipettor	Remove liquid carefully, press ENTER to confirm.
STATE Wash station full	Waste Water Tube is bended or not connected to analyzer	Check correct connection of tube; refer to Fatal errors if problem still exists!
STATE Out of washer liquid	Too less washing solution	Refill washing solution to rotor position R1.

7.3 Non-Fatal Errors

Message	Cause	Corrections
ERROR Write protected card	A protected ChipCARD was used to save a method.	Repeat procedure with a non-protected ChipCARD.
ERROR No valid test card	The ChipCARD is invalid.	Repeat procedure with a valid ChipCARD.
ERROR no writing	ChipCARD or reader is defective. Chip CARD was insert wrong.	Use new ChipCARD or insert correctly. Otherwise contact customer service.

Module: <Name> (<Adr>)
ParBlock Error <Nr>
 	
Example:
`Module: Meas1 (0A)`
`ParBlock Error2`
	Check sum error in the memory.	The system loads all default parameters automatically. Check method and instrument data. Some parameters might have to be redefined. See Chapter 6.2.1, 6.2.2, 6.4

break bot lim	Sample is too turbid, too dark and cannot be measured.	Prepare new test and repeat measurement. If this message appears often contact the customer service.
break top lim	Sample is very light and cannot be measured.	Prepare new test and repeat measurement. If this message appears often contact customer service.
Too dark	Sample is too dark and cannot be measured.	Prepare new test and repeat measurement. If this message appears frequently contact the customer service.
break drift	The measuring signal could not be adjusted or is unsteady	Check reagent and tubes for particles.
break noise	strong noise during sample adjustment.	Check for air bubbles or particles.
break jump	signal peak during measure	Check sample for air bubbles.
No clotting found	No clotting was found during maximum measuring time.	Check the max meas time. Dilute sample and repeat measurement.
Time Range error	The permissible deviation of CV's was exceeded.	Repeat measurement.
Conc. Overflow	The extrapolation range was exceeded during conversion.	Check reference curve and repeat measurement. This message does not necessarily mean a wrong result.
Conc. Underflow	The extrapolation range was not reached.	Check reference curve and repeat measurement. This message does not necessarily mean a wrong result.
Normal Range	The result is out of the normal range.	Check normal ranges unless it is sure that the patient really is outside the normal ranges.

7.4 Fatal Errors

Message	Cause	Corrections
Module: Control (07) Move Error Motor 1	X-motor is blocked and/or does not reach its normal value. X-motor is not connected properly or can not reach its home-position.	Check whether the pipettor can move freely from right to left Otherwise contact customer service.
Module: Control (07) Move Error Motor 2	Z-motor is blocked and/or does not reach its normal value. Z-motor is not connected properly or can not reach its home-position.	Check whether the pipettor can move freely up and down. Otherwise contact customer service.
Module: Diluter (03) Move Error Motor 1	Functional failure at the diluter valve.	Contact customer service.

Module: <Name> (<Adr>)
Range Error Par <Nr>
 	
Example:
`Module: Meas1 (0A)`
`Range Error Par 1`
	Functional failure in the module communication.	Contact customer service.

mixer error	One or more stir motors in the measuring cell are defective.	Contact customer service.

Module: <Name>(<Adr>)
Syntax Error Par <Nr>
 	
Example:
`Module: Control (07)`
`Sytax Error 0`
	Functional failure in the module communication.	Contact customer service.

Module: <Name>(<Adr>)
Com. Error <Nr>
 	
Example:
`Module: Control (07)`
`Com. Error 0`
	Functional failure in the module communication.	Contact customer service.

Module: <Name>(<Adr>)
Command Error <Nr>
 	
Example:
`Module: Meas1 (0A)`
`Command Error 2`
	Functional failure in the module communication.	Contact customer service.

Module: <Name> (<Adr>)
Unknown Error
 	
Example:
`Module: Control (07)`
`Unknown Error`
	Functional failure in the module communication.	Contact customer service.

STATE Wash station full	Waste water pump defective.	Contact customer service, first refer to application errors!
Temperature error	The temperature is not stable during the measurement.	Contact customer service.

Message	Cause	Corrections
Parameter error System stopped!	Severe soft- or hardware failure.	Contact customer service.

<Name>(<Adr>) not found
System stopped!
 	
Example:
`Dilutor (03) not found`
`System stopped!`
	Severe soft- or hardware failure.	Contact customer service.

Module: Control (07) Move Error Motor 0	Rotor motor does not reach home-position or is not connected properly.	Contact customer service, or see application errors!
Module: Control (07) Move Error Motor 3	M-Block motor does not reach home-position or is not connected properly. Light barrier is damaged.	Contact customer service, or see application errors!

7.5 Change fuses

Fuses may need to be changed if the system does not operate even though it is properly connected.

Two fuses are required to operate the system:

230 VAC (Europe)	115 VAC (USA)
4 amp/250 V time lag according to: IEC 60127-2/III	4 amp/125 V time lag according to: UL 248-14

Proceed as follows to change fuses:

- Switch off system
- Disconnect system from power supply and remove cable.
- Carefully lift the housing cover open, pull 1 (see figure 16).
- A red fuse carrier (= voltage selector) becomes visible.
- Place the screwdriver in the upper slot of the fuse carrier, pull 2 (see figure 16) and drive carrier out of the housing.
- Inspect fuses to see if wires have melted and replace accordingly.
- Insert fuse carrier into housing.
- Close cover of the fuse carrier.
- Reconnect the system to power supply and check proper operation.

Contact the authorised customer service if the exchange of fuses has been unsuccessful.

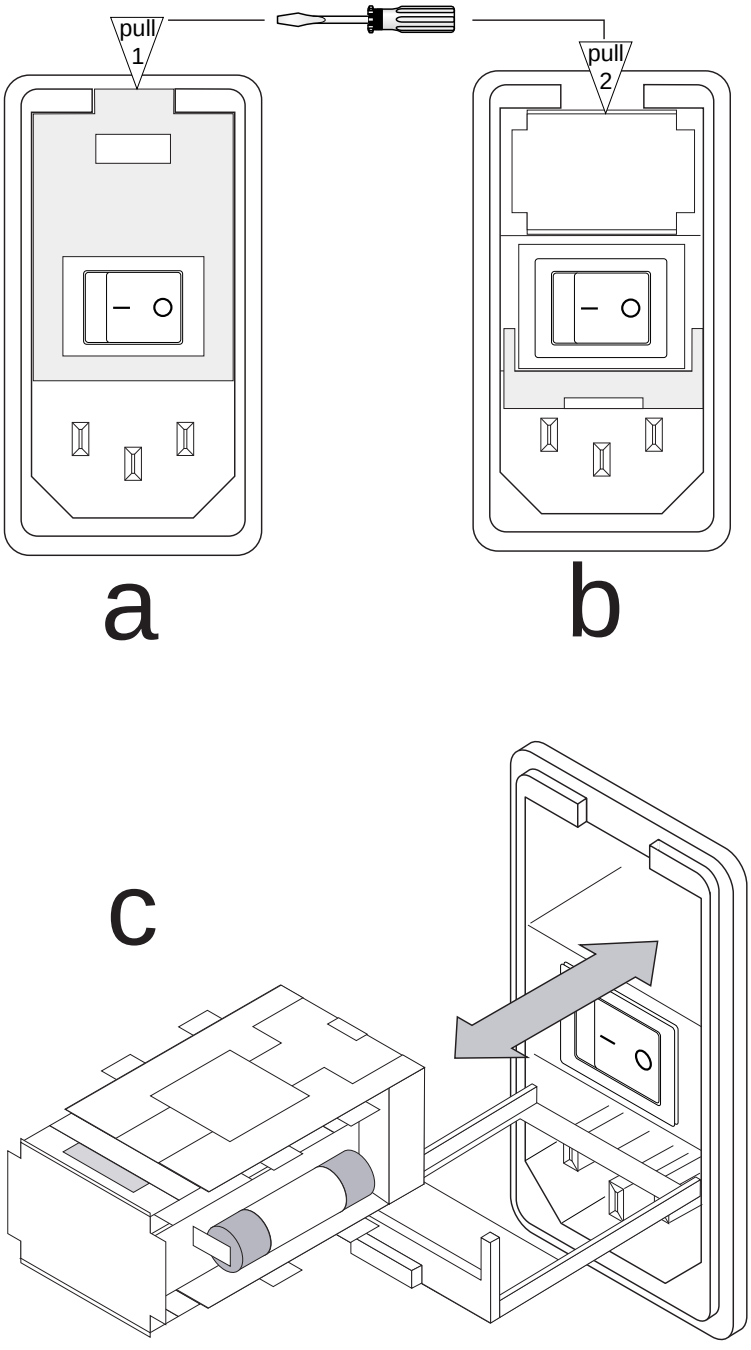


Figure 16 Change fuses

8 Annex

8.1 Maintenance and Hygiene

Watch the important cleaning and hygiene instructions which have to be followed regularly, according to the list below.

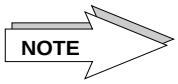
To obtain accurate and precise results the manufacturer recommends cleaning and maintaining the system regularly. Disregarding these instructions may cause contamination and operational failures of the system and may also lead to the manufacturer's warranty becoming null and void.

Carefully observe the following cleaning and hygiene instructions:

Step	Cycle				described in **chapter**	Service **needed**	
	daily	weekly	monthly	yearly		yes	no
Rinse with washing solution	1x				6.1.4		X
Disinfect tubing's (Terralin)			2x		6.1.3		X
Clean distilled Water Container (70% alcohol solution)			1x		6.1.13		X
Clean Waste Water Container (70% alcohol solution)			1x		6.1.14		X
Clean and disinfect housing (70% alcohol solution)		1x			8.1.1		X
Replace fresh water filter at distilled water sensor (green)			1x		6.1.3		X
Clean waste box		1x			8.1.1		X
Replace tubing's				1x	5.1.4.1		X
Replace 250 µl syringe				1x	5.1.4.1		X
Replace distilled + waste water container				1x	5.1.4.2		X
Replace pipettor (recommended)				1x		X	
Replace dilutor valve (recommended)				1x		X	

8.1.1 Cleaning and Disinfection of housing and waste box

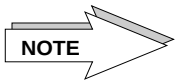
Once a week the housing and the waste box should be cleaned and disinfected to avoid any contamination.



Do not use organic acids.

Do not use any organic acids to clean the instrument and the waste box. Only use a cleaner designed for cleaning and disinfecting instrument surfaces and waste box. Use a dampened cloth. Never spray or pour any liquids onto or into the system which may negatively impact the analyzer's functions.

If liquids have accidentally run into the system contact the customer service of the distributor or the manufacturer.



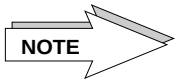
Avoid any direct skin contact with samples and/or test reagents as well as those parts of the instrument which might be contaminated with samples and/or test reagents.

These parts are potentially infectious. If samples were spilled onto the system wipe them off immediately and disinfect the instrument. Reagents might irritate the skin or mucous membranes. Observe the manufacturer's instructions in the package insert how to handle the reagents properly.

Make sure to dispose of the sample and test material in compliance with biohazard and legal provisions.

8.1.2 How to dispose of used disposables

Remember to dispose of used cuvette racks, primary tubes, and reagent vials in compliance with legal provisions.



All disposables used with the system must be treated as potentially infectious. Avoid any skin contact with sample and reagent material which might be on the disposables.

Dispose of used disposables in compliance with legal provisions or laboratory regulations. Do not put used disposables, samples and reagents into the usual garbage.

Cuvette racks might not be resistant to organic acids. Therefore do not use organic acids unless they are expressly permitted.

8.1.3 How to dispose the used system

Remember the disposal of the used complete system incl. all tubing's, syringe etc. must be done in compliance with all relating legal provisions. The used system and its parts are hazardous waste and must be treated as potential infectious. Ask your local dealer or distributor for further directions.

8.2 Protocol of Maintenance Check

The manufacturer recommends recording all maintenance check-ups of the system in which all service, maintenance and repair, replacement of parts, cleaning and disinfection cycles will be documented.

On the last page of this chapter you will find a Maintenance Check form which you should copy and use to protocol all information mentioned above.

In this form you can fill in all necessary information from initial operation to any later incidents.

If the customer service has to repair or replace parts on the system you should make the maintenance check protocols available. This might simplify the repair.

8.3 Safety Specifications

The instrument is in compliance to all relevant European regulations.

The instrument described in this manual bears a CE mark which confirms the compliance with the essential requirements of the following European directives:

If the instrument's type plate bears an IVD symbol, it complies with the following directive: - 98/79/EC In-vitro diagnostic directive

If the instrument's type plate bears no IVD symbol, it complies with the following directive: - 73/23/EEC low voltage directive
- 89/336/EEC-EMC directive

Suppression of radio interference
The system was tested to meet the following standards and was classified class B:
EN 50081-2 Emission
EN 55011, Class B
EN 50082-2 Immunity
EN 60601-1-2
EN 61000-4-2, -3, -4, -5, -6, -11, EM 50204, IEC SC 77A WG6

To meet the above standards it is necessary to use screened data cables. The user is responsible for the use of screened data cables.

8.4 Technical Data

In this chapter the application, technical data and the ranges which must be observed when operating the system are described.

Application

The system is an automatic coagulation analyzer to be operated with the six fold cuvette rack system.

Proper Operation

The system may be operated by skilled personnel and in specially designed rooms only. It may exclusively be used for *in-vitro* diagnostic testing, especially to analyse blood coagulation. All instructions from this manual, especially chapter 2 Hazard and Precaution must be observed.

Technical data

General description

Instrument type:	*In-vitro* diagnostic fully automated coagulation analyzer
Application:	Clotting coagulation tests such as PT, aPTT, Fibrinogen
Operation:	Batch mode (test selective) Random-Access Mode (Sample Oriented)
Measuring principle:	Turbodensitometric, opto-mechanical with automatic adjustment and magnetic stir bar to homogenize the sample, thereby increasing the sensitivity.
Measuring timer:	Internal clock module, possible error < 0.1 sec.
Sensitivity:	PT > 10% of standard
Throughput:	PT: ~ 120 tests per hour (batch) aPTT: ~ 50 tests per hour (batch) Fibrinogen: ~ 50 tests per hour (batch)
Light source:	LED´s Light Emitting Diode, Light intensity depending on turbidity of sample.
Measuring channels:	6 channels
Primary rotor:	For 6 cuvette bars each, each cuvette bar contains 6 wells, 18 sample positions, 6 reagent positions R1-R6
Max. test volume:	250µl
Sampling:	X-Z pipetting device to transport plasma and reagent. The pipettor is heated to 37 ^{O}C. A level sensor checks the liquid levels of reagents and samples.
Dilutor:	250µl syringe, 1 distilled water tube, 1 waste water tube.
Reagent positions:	6 positions for reagents, plasma and washer at room temperature.
Software:	Test menu for PT, aPTT and Fibrinogen Documentation of all test parameters Reference curves Date / Time Conversions into %, g/l, mg/dl, Ratio, INR Entry of all reagent specific data via ChipCARD Service program
Special features:	Single or double determination Integrated waste box for used cuvette bars PT plasma or reagent start APTT plasma or reagent start Fibrinogen pre-pipetting optional Optimal cuvette consumption

Display	Alphanumeric LCD display with two lines of 20 characters each.
Printer:	Built-in thermal printer Paper roll 57 mm wide
Interfaces:	RS 232 C Host/Service Barcode scanner
Barcodescanner optional:	Entry of patient and plasma identification.
Noise emission:	< 70dB (A)

Physical data:

Voltage:	100 - 240 V	
Frequency:	47 - 63 Hz	
Capacity:	150 VA	150 VA
Fuses:	4A/250 V time lag IEC 60127-2/III	4A/125 V time lag UL 248-14

Ambient temperature

temperature:	during operation during transport	+10C - +30C +10C - +45C
humidity:	10% - < 85%, non-condensing	

Dimensions

Instrument (WxHxD):	72 x 55 x 45 cm	27.7 x 21.2 x 17.3 in.
Shipping:	72 x 60 x 53 cm	27.7 x 23.1 x 20.3 in.

Weight

Instrument:	17 kg	35 lb
Shipping:	18 kg	38 lb

8.5 Accessories and Consumables

All accessories and disposables to be used with the system will be described. All item numbers to order the appropriate material will also be referred to.

Accessories with initial delivery
Item No. 30.000.1218

Consisting of:	Quantity
Distilled Water Container incl. screw lid	1
Waste Water Container incl. screw lid	1
Cleaner Container incl. screw lid	1
Distilled Water Sensor	1
Waste Water Sensor	1
Filter for Fresh Water Sensor	12
250 µl syringe	1
Tubing incl. tubing carrier	1
Bottle with Washing Solution	5
Bottle with Cleaning Solution	1
Fuses for 230 VAC	2
Fuses for 115 VAC	2
Paper Roll Holder	1
Paper Internal Printer	1
Operator Manual English	1
ChipCARD w/ factory defaults	4
ChipCARD blank	2
Cuvette Bars (6wells) w/ Mixer 1x3mm	10
Sample Cups	20
Reagent Vial 10 ml	6
Adapter Vial 10 ml	6
Reagent Vial 4 ml	6
Adapter Vial 4 ml	6
Teflon Mixer 3x13mm	2
CPC-Plug	1
Waste Box	1

Special accessories

Description	Quantity	Item No.:
Barcode Scanner	1	30.000.1134
ChipCARD PT	1	30.000.1196
ChipCARD aPTT	1	30.000.1228
ChipCARD Fibrinogen (g/l)	1	30.000.1229
ChipCARD Fibrinogen (mg/dl)	1	30.000.1161

Consumables

Description	Quantity	Item No.:
Cuvette Bars (6 wells) w/ Mixer 1x3 mm	1x100	40.000.0059
Sample Cup 4ml	2x250	40.000.0063
Reagent Vials 10 ml (3 x 25)	75	30.000.1238
Reagent Vials 4 ml (2 x 25)	50	30.000.1148
Teflon Mixer	2	30.000.1233
Paper for Internal Printer	10	30.000.0982
Fuses for 230 VAC	10	30.000.1617
Fuses for 115 VAC	10	30.000.1618
Washing Solution (15 ml bottle)	5	30.000.1151
Cleaning Solution (15 ml bottle)	5	30.000.1149
ChipCARD blank (for data storage)	10	30.000.1199
CPC-Plug	1	30.000.1337
Kaolin Suspension (5x13ml)	5	30.000.1096

Maintenance kit

Item no. 30.000.1400

Consisting of:	Quantity
Tubing for Pipettor, incl. tube carrier	1
Distilled Water Container, incl. screw lid	1
Waste Water Container, incl. screw lid	1
Fresh Water Filter	12
Distilled Water Sensor	1
Waste Water Sensor	1
250 µl syringe	1

Technical documentation

Description	Quantity	Item No.:
Operator Manual English	1	30.000.1616
Operator Manual German	1	30.000.1615
Instrument Control Card (ICC) German	1	20.000.3068
Instrument Control Card (ICC) English	1	20.000.2947

8.6 Mathematics

Conversion Ranges

The conversion ranges are fixed in method parameterisation program and cannot be modified by the user.

Interpolation:

Polygonal: from measuring point to measuring point
Regression: optimised line of all measuring points

Extrapolation:

PT: > 100% Extrapolation over the last two upper measuring points
Extrapolation factor: 1.5

PT: < 10% Extrapolation over the last two lower measuring points
Extrapolation factor: 0.5

Fibrinogen: Extrapolation over the last two measuring points

Conversion to INR:

INR	=	$\text{PT - Ratio}^{\text{ISI}}$
INR	=	International Normalised Ratio
PT-Ratio	=	measured value in seconds divided by 100% value in seconds
ISI	=	International Sensitivity Index according to package insert

8.7 Adaptation of coagulation reagents

In ROUTINE MENU you can install a maximum of three different methods. In general a wide variety of coagulation reagents can be used on the system. Remember that not for all reagents on the market a suggestion of adaptation could be determined by manufacturer. The use of different reagents may require specific changing's on the system settings.

On request manufacturer will only provide a suggestion on how to adapt some specific reagents on the system. The responsible adaptation and release of reagents is object to users respectively distributors internal laboratory regulations.

Add a kaolin suspension to the reagent for fibrinogen determinations.

All reagents can be stirred with the stir bar (2 pieces supplied).

For further information with regard to adaptation of reagents contact the Service + Support Department of the manufacturer or your local Distributor.

8.8 Packing of the system, preparation of transport

Adhere to the following instructions when transporting the system (e.g. for service reasons).

Use only those packing materials received initially with the instrument.

1 If the system has been used, ensure the housing, sample/reagent rotor and waste box have been disinfected thoroughly, see Section 8.1 Maintenance and Hygiene.

2 All tubing's, distilled water and waste water tubes must be rinsed thoroughly before packing. See Section 6.1.3 Disinfection of waste tubing (Terralin), change of FW-Filter for further information.

3 Empty the dist. water pump so it will not be damaged during transport due to possible temperature fluctuations.

4 Disconnect adapter of fresh water tubing on the back side of the system, see Section 5.1.4.2.

5 Replace with the CPC-connector provided in the accessory box. To empty the distilled water pump remove the distilled water tube from the container and hold it over a sink. Then rinse the tubing 5 times, see Section 6.1.2. Stop this procedure immediately if you hear an abnormal sucking noise from the pump.

6 Remove the CPC-connector and return it into the accessory box.

7 Empty and clean the distilled and waste water containers as described in Section 6.1.13 and 6.1.14 for further information.

8 Remove all cuvette bars, primary tubes and reagent vials from the system.

9 Secure the system with all transport protection devices as per Section 5.1.3 Unpacking the system.

10 Pack all accessories into the supplied boxes and carefully close them.

11 Pack the system into the foam parts and place it into the outer box.

12 Place the accessory box into the outer box.

13 Close the carton carefully.